Validation of the automatic blood pressure measurements device, the OMRON M3 COMFORT (HEM -7134-E) ® in Pregnancy according to the Modified European Society of Hypertension International Protocol (ESH-IP).

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Signature

Introduction

For many years, the gold standard instrument for blood pressure (BP) measurement was a mercury sphygmomanometer and a stethoscope, but this century-old technique of Riva-Rocci/Korotkov is being progressively removed from clinical practice because of the mercury toxicity and the number of errors that may taint this method[1,2]. Several non-mercury techniques have been developed during the last ten years in order to gradually supplant the mercury-auscultatory method[3,4], such as the automatic electronic devices using algorithms based on the oscillometric technique[5,6]. It is evident that these devices need to go through a validation by experts in independent centers as recommended and requested by guidelines and societies. Different protocols are used to validate the accuracy of BP measuring devices such as the International protocol published by the working group on BP monitoring of the European Society of Hypertension (ESH)[7], the British Hypertension Society (BHS) protocol and the Association for the Advancement of Medical Instrumentation (AAMI) protocol[8,9]. Over the last ten years, several automated devices have been successfully validated using established protocols[10], mostly on the general population. However, few studies have tested the accuracy of automated BP monitors in specific populations such as diabetic patients[11], pregnant women[12], obese[13,14], elderly[51], and in arrhythmic patients[16-18].

Pregnancy is a specific condition where vascular hemodynamic and arterial function and structure changes influence the arterial signals and therefore the blood pressure determination. In this regard, all the validations protocols recommend, for blood pressure devices designed to be used in pregnancy, to go through specific validation of their accuracy in this specific population. Only few devices have been shown accurate in pregnant women with and without pre-eclampsia[19-22].

The objective of this study is to assess the accuracy of the automatic inflationary oscillometric BP measurements at the brachial level of the OMRON M3 COMFORT (HEM -7134-E) ® device in pregnant women including pre-eclampsia according to the modified ESH International protocol.

Methods

Ethical committee

This prospective study using a medical device of Type IIA was submitted and approved by the ethical committee of the L.A. Ohanesyan Institute of Cardiology, Armenia. All subjects included in this study provided a written informed consent.

Study population

According to the modified ESH-IP, 45 women were included. Pregnancy and pre-eclampsia: Include 45 women in 2nd and 3rd trimesters of pregnancy, of whom 15 with pre-eclampsia defined as elevated BP with proteinuria, 15 with gestational hypertension (new onset in pregnancy with BP ≥140 mmHg and/or ≥90 mmHg without proteinuria), and 15 normotensives.

Inclusion criteria & Non-inclusion criteria were:

	Inclusion criteria	**Non-Inclusion Criteria**
PREGNANT WOMEN	- Age > 18 years - In-patient or out-patient - Informed consent - Known Pregnancy > 3 months - Treated or untreated - Normotensive, hypertensive and pre-eclampsia	-Heart rhythm: Arrhythmia -Poor quality Korotkov sounds -Absence of K 5 sounds -Arm circumference > 42cm

Procedures & Measurements

Tested Device: The OMRON M3 COMFORT (HEM -7134-E) ® device was provided by Omron Healthcare company. Three devices were provided, one of them has been randomly chosen to perform the study. This is a digital automatic device for home BP measurement at the arm level. The monitor uses inflation by Fuzzy-Logic controlled by electric pump and an automatic rapid pressure release valve for the deflation. The monitor weight is approximately 300 g (not including the 4 “AA” needed batteries); its cuff allows BP measurements in arm circumference of 22-42 cm. The device measure BP and pulse rate with a pressure range of 0-299 mmHg and pulse rate range of 40-180 beats/min. Systolic BP (SBP), diastolic BP (DBP) and pulse rate are displayed on a liquid crystal digital (LCD) screen. Additional technical details can be obtained from the User-Manuals. The device has been used according to the manufacturer recommendation.

Mercury Sphygmomanometer blood pressure Measurements: The validation team consisted of three persons, two observers and one supervisor trained in accurate BP measurement. 45 pregnant women had their BP measured by the two observers using parallel connected mercury sphygmomanometers and a “Y” connected teaching stethoscope, blinded from each other's result, and then by the supervisor using the tested device. The agreement between the 2 observers was checked all over the evaluation period by the supervisor to make

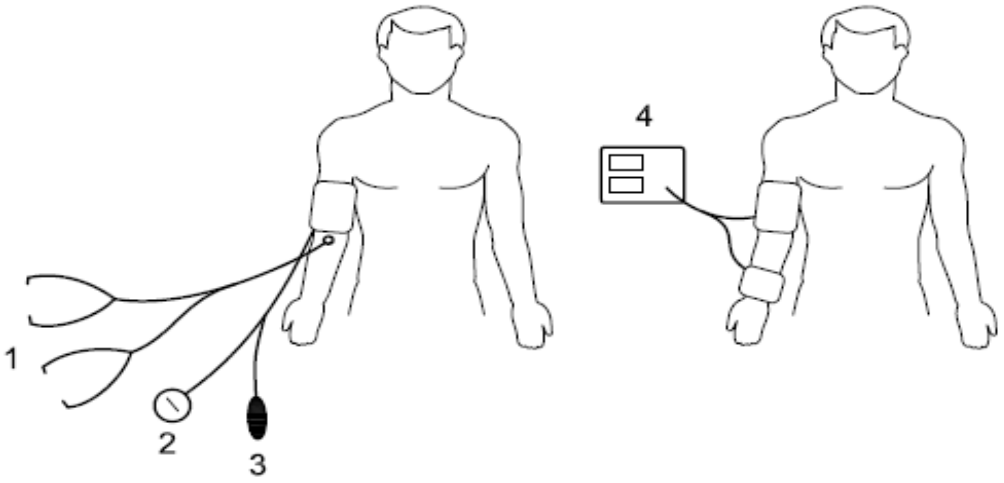
sure that the difference between the two observers is no more than 4 mmHg for systolic and diastolic BP values. Otherwise, the measurement should be repeated. Korotkov K5 sound was used for reference diastolic BP.

Two standard mercury sphygmomanometers were used by the 2 observers as a reference standard. The circumference of the arm was measured to ensure that the reference cuff-size being used is adequate for the subject (Table 1). Measurements were performed according to the "same *arm, consecutive measurements*" method on the left arm supported at heart level (Figure 1). Measurements by the OMRON M3 COMFORT (HEM -7134-E) ® device was performed on the same arm supported at the heart level as recommended by the manufacturer. The following procedure was followed:

a) Ask the subject to relax for 5-10 min.

b) make sure that the subject is seated with legs uncrossed and back supported.

Figure 1: Illustration of the same arm sequential method



Key

ouble stethoscope

2 **reference sphygmomanometer** display

3 **reference sphygmomanometer** hand pump

4 **sphygmomanometer-under-test**

In total, nine consecutive BP measurements were performed in each woman using the mercury sphygmomanometers (5 times) and the tested devices (4 times).

All nine-sequential same-arm measurements were recorded as shown in Table 2, starting with the standard mercury sphygmomanometer.

Table 1: Cuff sizes and corresponding arm circumferences used for the standard method

Cuff Size	Small	Medium (standard)	Large
Arm circumference (cm)	17-22	22-32	32-42

Table 2: Sequential measurements of BP recorded by the standard mercury sphygmomanometer and the tested device:

BPA	Entry BP, observers 1 and 2 each with the mercury standard
BPB	Device detection BP, supervisor
BP1	Observers 1 and 2 with mercury standard
BP2	Supervisor with the test instrument
BP3	Observers 1 and 2 with mercury standard
BP4	Supervisor with the test instrument
BP5	Observers 1 and 2 with mercury standard
BP6	Supervisor with the test instrument
BP7	Observers 1 and 2 with mercury standard

The first auscultatory and the first device measurement represent the recruitment pressures (BPA and BPB). For each subject, the device measurements BP2, BP4 and BP6 were first compared to observer measurements BP1, BP3 and BP5 respectively and then to observer measurements BP3, BP5 and BP7, respectively. Comparisons more favourable to the device were used. BP1, BP3, BP5 and BP7 were used to calculate the means of the 2 observer measurements.

Subjects were recruited to fulfill the recommended criteria as shown in Table 3.

Table 3: Recommended criteria of included pregnant women.

2nd & 3rd trimesters of pregnancy	
15 normotensives	<140/90 mmHg
15 with hypertension & without proteinuria	≥140 mmHg and/or ≥90 mmHg
15 with pre-eclampsia	≥140 mmHg and/or ≥90 mmHg with proteinuria

Statistical Analysis

Results are analysed and expressed according the protocol to conclude if the device passes or fails to pass the validation protocol requirements. The statistical analysis was performed using specific analysis software. The device measurement was compared to each individual observer

mean readings taken before and after, resulting in two sets of three differences (one set for comparisons “before” and one set for comparison “after” for systolic and diastolic blood pressure values separately. The set of differences that is more favorable to the test device was retained for the final statistical analysis. The numbers of ‘A’s, ‘B’s, ‘C’s, and ‘D’s were used in the analysis to calculate the number of device-observer differences within 5 mmHg, 10 mmHg, 15 mmHg and > 15 mmHg. To be recommended for clinical use, a device must achieve a grade A or B for both systolic and diastolic blood pressure. An additional evaluation was also performed based on the AAMI criteria, requiring a mean difference between the device and the observers means of ≤ 5 ± 8 mmHg. The Bland–Altman graphs are used to show the device–observer differences versus average device and observer values for all pairs of comparisons.

Results

Device Details

Brand	OMRON
Model	M3 COMFORT
Manufacturer	OMRON
Location	Upper Arm
Method	Oscillometry
Purpose	self/home measurement
Operation	Automatic
Arm Cuffs device	
Arm Cuffs mercury	
Other features	

Screening and Recruitment Details

Screening and Recruitment		
Total Screened		60
Total Excluded		15
Ranges Complete	0	
Range Adjustment	0	
Arrhythmias	0	
Device Failure	0	
Poor Quality Sounds	0	
Cuff Size Unavailable	0	
Observer Disagreement	0	
Distribution	0	
Other Reasons	15	
Total Recruited		45

Recruitment Ranges		mmHg	All
SBP	Low	< 90	0
		90-129	16
	Medium	130-160	29
	High	161-180	0
		> 180	0
DBP	Low	< 40	0
		40-79	15
	Medium	80-100	28
	High	101-130	2
		> 130	0

Subject Details

Sex	Male:Female	0:45	
Age (years)	Range (Low:High)	18:38	
	Mean (SD)	28.6 (4.0)	
Arm Circumference (cm)	Range (Low:High)	22:34	
	Mean (SD)	28.0 (3.0)	
Cuff for Test Device	Standard	22-42 cm	
		0	
Mercury Cuff	Small	0	
	Standard	40	
	Large	5	
		SBP	DBP
Recruitment BP (mmHg)	Range (Low:High)	90:152	53:104
	Mean (SD)	129.7 (19.0)	84.0 (14.0)

Observer Measurements in each Recruitment Range

SBP (mmHg)		DBP (mmHg)	
Overall Range (Low:High)	88:151	Overall Range (Low:High)	52:104
Low (< 130)	61	Low (< 80)	46
Medium (130 – 160)	74	Medium (80 – 100)	86
High (> 160)	0	High (> 100)	3

Observer Differences

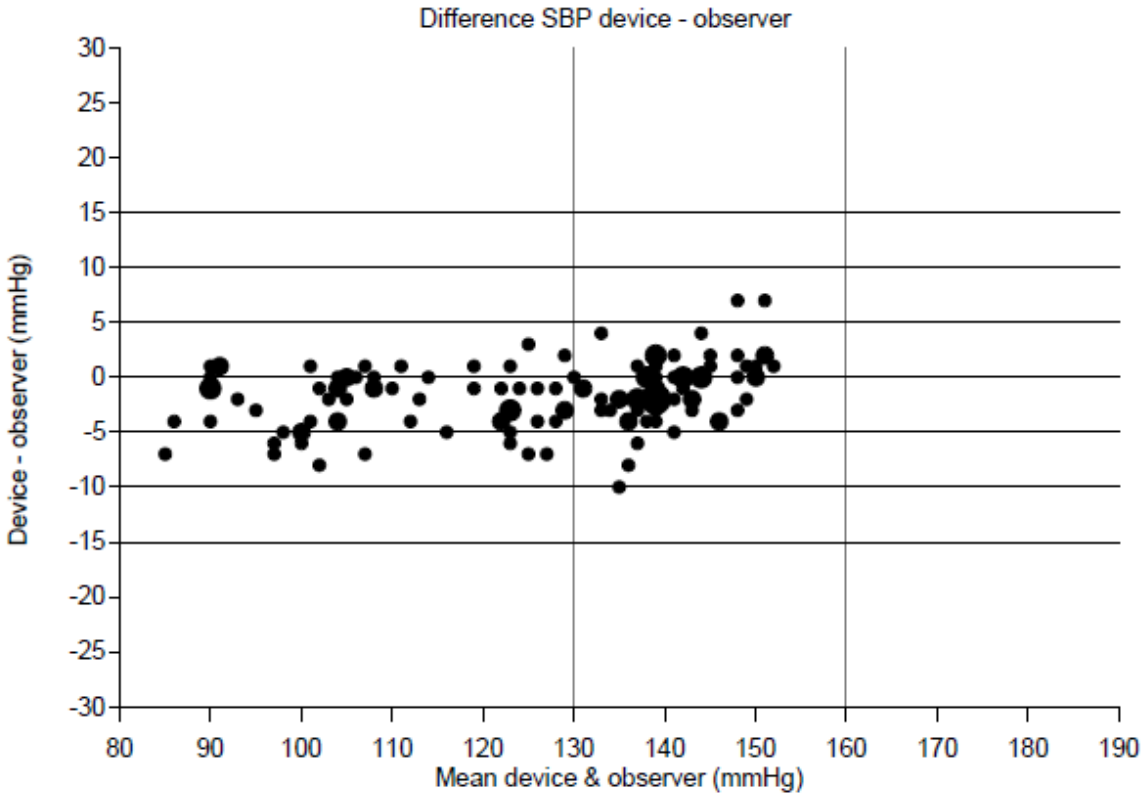
		SBP (mmHg)	DBP (mmHg)
Observer 2 – Observer 1	Range (Low:High)	-4:+2	-4:+4
	Mean (SD)	-0.1 (0.9)	+0.0 (1.1)

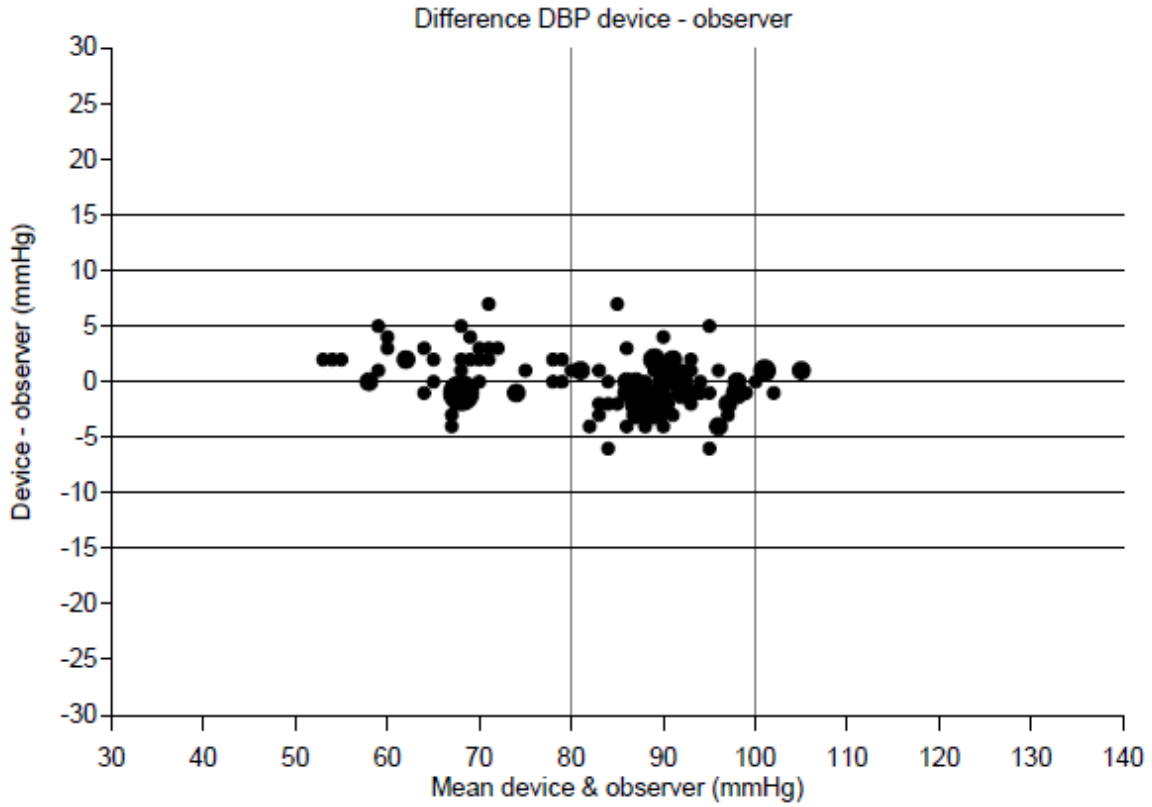
Validation Results

Part 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade 1	Mean mmHg	SD mmHg
Pass Req.	Two of	73	87	96			
	All of	65	81	93			
Achieved	SBP	121	135	135	Pass	-1.6	2.8
	DBP	131	135	135	Pass	-0.1	2.3

Result: Pass

	GRADE A, B, C			
	<=5mm	<=10mm	<=15mm	**GRADE**
SBP %	90%	100%	100%	**A**
DBP %	97%	100%	100%	**A**
SBP nb	121	135	135	
DBP nb	131	135	135	





This study showed the accuracy of the Omron M3 Comfort (HEM -7134-E) oscillometric device by fulfilling the modified International Protocol acquires. The results showed a classification grade A for both the systolic and diastolic BP. The mean differences between the observer and the device measurements were -1.6 ± 2.8 mmHg and -0.1 ± 2.3 mmHg for systolic and diastolic BP respectively (< 5±8 mmHg).
However, it should be emphasized, that each subject was in a correct position, the arm supported at the heart level and the device was used according to the manufacturer recommendations. These conditions must be respected in clinical practice.

This validation has been performed in pregnant women (normotensive, hypertensive and pre-eclampsia); therefore, the results cannot be extrapolated to other specific populations such as the elderly, obese, children or other populations.

Conclusion

The OMRON® M3 COMFORT (HEM -7134-E) ® device fulfils the recommendations of the modified international validation protocol with grade A classification for both systolic and diastolic BP. Therefore, it can be recommended for clinical use in this population.

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dabl Educational Trust Limited
Att. Mr William RICKARD
Carraig Court, Georges Avenue
Blackrock, Co Dublin, Ireland

Paris, January 20, 2018

Subject: Listing in dabl website of Omron M3 Comfort & Omron EVOLV

Dear Bill,

I am writing you regarding the Omron M3 Comfort and the Omron EVOLV who have been validated by my team in pregnant women. These two devices are listed on the dabl education website as to be used in “clinical setting”.

This classification as “clinical setting” may be the consequence of the report conclusion mentioning that “the devices can be recommended for clinical use”. Sorry about that because what we wanted to say is that these devices can be recommended by physician for self-blood pressure measurements. In fact, as described in the “Methods – Tested device” section of the reports, these two devices are for home BP measurements.

Therefore, I here undersigned certify that the two devices, the Omron M3 Comfort and the Omron EVOLV devices validated by my team according to the International Protocol of the European Society of Hypertension in pregnant women, are as described in the “Methods-Tested device” section in each of the corresponding report, for self-BP measurements and have been validated accordingly. Wording in the conclusion section “recommended for clinical use” which may bring misunderstanding, meant that these two devices can be recommended by physician in clinic for a patient self-BP measurement.

In this regard, may I ask you to change the listing of these two devices from “clinical setting” to “self BP measurement”. This is important to be in accordance with the future publication we are planning to do.

Sorry about this misunderstanding.

My best wishes for 2018.

Kind regards.

Pr Roland ASMAR

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