Validation of the TONOPORT VI ambulatory blood pressure monitor, according to the European Society of Hypertension International Protocol revision 2010

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Objective: The present study aims to examine the performance of the TONOPORT VI ambulatory blood pressure measurement (ABPM) device in the inflation measurement method and the deflation measurement method, according to the European Society of Hypertension International Protocol revision 2010 (ESH-IP 2010).
Materials and Methods: Systolic and diastolic blood pressures (SBP and DBP, respectively) of 33 subjects (23 female, 10 male) were sequentially measured and compared with reference measurements obtained by two observers using a standard mercury sphygmomanometer. The subjects were selected according to the recruitment instructions of the ESH-IP 2010. Three comparative readings were performed per subject.
Results: The numbers of differences between reference and device in the inflation measurement method were for SBP 92/97/98 (≤ 5 / ≤ 10 / ≤ 15 mmHg) and for DBP 94/99/99 (≤5/≤10/≤15 mmHg). Similar numbers were obtained in the deflation measurement method, with 93/98/99 (≤5/≤10/≤15 mmHg) for SBP and 91/98/99 (≤5/≤10/≤15 mmHg) for DBP. Each time, all Subjects had at least 2 out of three comparative readings with differences ≤ 5 mmHg and no subject had no reading ≤ 15 mmHg.
Conclusion: The TONOPORT VI respectively in the inflation measurement method and in the deflation measurement method met all requirements of Part 1 and 2 of the ESH-IP 2010. Based on the study results, the TONOPORT VI can be recommended for blood pressure measurements in adults.

Keywords: ABPM, ESH, validation, TONOPORT VI

Study Details

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Date	11.04.2016
Signature	

Device Details

Brand	GE Medical Systems Information Technologies, Inc.
Model	TONOPORT VI
Manufacturer	PAR Medizintechnik GmbH & Co. KG, Berlin, Germany
Location of cuff	Upper arm
Method	Oscillometric
Purpose	Ambulatory Blood Pressure Measurements
Operation	Automatic
Arm cuffs	Small: 17 cm to 26 cm Standard: 24 cm to 32 cm Large: 32 cm to 42 cm Extra Large: 38cm to 46 cm
Other features	Measurement during cuff inflation or cuff deflation

Introduction

Out-of-Office blood pressure (BP) measurements offer several advantages compared office BP readings, yielding in a rising prognostic value of ambulatory blood pressure monitoring (ABPM) or home blood pressure measurements (HBPM) [1]. Naturally, both methods depend on devices, where detailed information on quality and uncertainty of BP readings is decisive for their diagnostic value. The International Protocol (IP) published by the European Society of Hypertension (ESH) presents a widely accepted standard for validation of ABPM devices, enabling comparison and providing profound information on measurement performance under varying pressure levels. The constant technical progress in ABPM devices leaded the ESH to publish the ESH-IP revision 2010 [3], an improvement of the original ESH-IP revision 2002 [4], implementing stricter pass criteria and standardized data presentation [2]. This study aims to evaluate the accuracy of the TONOPORT VI, a new oscillometric device for ABPM monitoring, according to the ESH-IP revision 2010 [3].

Device Details

The TONOPORT VI is a recently developed oscillometric device for ABPM, offered by PAR Medizintechnik GmbH & Co. KG, Berlin, Germany. Compared to its predecessor TONOPORT V, the TONOPORT VI offers a new measurement method, where blood pressure is estimated during the inflation of the cuff, resulting in a lower measurement time and thereby more patient comfort. Upon request, the device can also perform a measurement during deflation of the cuff, similar to its predecessor TONOPORT V, which was validated according to the ESH-IP revision 2002 [4], in 2003 [6] and in 2005 [5]. This study aims to investigate both, the inflation measurement method and the deflation measurement method of the TONOPORT VI.

Methodology

Familiarization

All supervisors and observers were licensed physicians, experienced in blood pressure measurement, and executed a familiarization procedure previous to the validation. Thereby several BP test measurements were taken using the TONOPORT VI in the inflation measurement method with an automatic subsequent deflation measurement, as performed in the validation. The supervisors were trained with the sequence and instructed to read out the results correctly. Furthermore, they were instructed in all safety regulations regarding the device and provided with the operator's manual. In addition, all supervisors and observers

were instructed in the rules of the ESH-IP 2010 [3]. The device functioned correctly and was determined as easy to handle.

Recruitment

Subject recruitment took place among new patients and hospital staff of the St. Joseph's Hospital in Berlin, Germany ("St. Joseph Krankenhaus" in German). For that reason, there were no patients on antihypertensive medication among the recruited subjects. Arrhythmia, poor quality Korotkoff sounds, and arm circumferences not suitable for any provided cuff size posed criteria for an exclusion of subjects. Informed consent was obtained from all subjects.

Procedure

The European Society of Hypertension International Protocol revision 2010 [3] for the validation of blood pressure measuring devices in adults was followed precisely. Since this study aimed to investigate both, the newly developed inflation measurement method and the conventional deflation measurement method of the TONOPORT VI, the device readings included both. This means that for each device reading, two sets of measurement results were provided on the LCD display. First, after performed inflation, the values for the inflation measurement method. Secondly, after the performed deflation, the values for the deflation measurement method. This procedure is valid, because the measurement time of inflation and automatic subsequent deflation measurement method is not increased, compared to a conventional deflation measurement method only. In the following, the term "device reading" comprises inflation measurement method and automatic subsequent deflation measurement method. Measurements took place in a quiet, temperature controlled room. Subjects were instructed to sit (legs uncrossed, back supported) with the arm supported at heart level. The arm circumference was measured, before a proper cuff was chosen and fitted to the arm. Validation measurements were performed after a resting phase of 10-15 minutes to allow cardiovascular stabilization. Two observers, blinded from each other, took reference measurements using a standard mercury sphygmomanometer (ERKAMETER 3000, ERKA, Bad Tölz, Germany) and a dual-earpiece stethoscope (KaWe Colorscop - Plano training stethoscope, KaWe, Asperg, Germany). Observer readings were checked immediately by the supervisor and repeated if they differed by more than ± 4 mmHg (total numbers in Table 4). The mean of baseline BP readings (BPA) from both observers functioned to categorize the subject into BP ranges. Subsequent, a baseline device reading (BPB) was performed. In the following, 7 alternating observer and device readings (BP1-BP7) were executed (starting and ending with observer). Hence, each device reading was adjacent to two observer measurements.

Processing

Data Processing was performed separate for inflation method and deflation measurement method. Therefore, Microsoft Excel 2010 was utilized to analyze SBP and DBP readings, respectively. First, connected observer measurements of observer 1 and 2 were averaged. Then, for each device reading (BP2, BP4, BP6), the adjacent observer mean, that deviated less, was chosen as corresponding reference value. Differences between device and reference were calculated and grouped into ≤ 5mmHg, ≤ 10mmHg, ≤ 15mmHg.

Results

Subjects

Recruitment of patients at high BP levels turned out more difficult, leading to 11 excluded patients for reasons of complete ranges (see Table 1). Further, one patient had to be excluded because of range adjustments and two patients in order to meet the distribution requirements of the ESH-IP revision 2010. In conclusion, out of 47 participants 33 subjects (23 female, 10 male) were enrolled in the study.

Observer Measurements

Table 4 illustrates the agreement between the two observers over all observer measurements (BP1, BP3, BP5, BP7), except the baseline reading (BPA). Four readings were repeated, because of observer disagreement by more than 4 mmHg. Table 3 lists the number of observer measurements within each recruitment range, respectively for inflation - and deflation measurement method. The dissimilar distribution among the ranges shows that BP readings varied from the initial baseline readings. Nevertheless, the distribution requirements of the ESH-IP 2010 were met after distribution adjustment (compare Table 1). The slight differences between inflation - and deflation measurement method arise from the circumstance that the adjacent observer mean, that deviated less, changed for some measurements.

Validation Results

The Table 5 list the differences between device and reference readings, along with the pass criteria of the ESH-IP 2010. For both, Part one and Part two of the protocol, the TONOPORT VI achieved all requirements by far, thereby passed the ESH-IP 2010. This applies on both, the inflation measurement method and the deflation measurement method of the device. In the inflation measurement method, each of the 33 subjects had at least two out of three comparative readings with differences ≤ 5 mmHg, for SBP and DBP respectively. The total number of readings with differences ≤ 5 mmHg was 92 out of 99 for SBP and 94 out of 99 for DBP and the total number of readings with differences > 10 mmHg was 2 out of 99 for SBP and 0 for DBP. Figure 1 visualizes an even distribution of device - observer disagreements

among pressure ranges in Bland-Altman plots. The majority of results are valuated below 5 mmHg. A dependency of the accuracy to the pressure level is not visible.

The results of the deflation measurement method differ slightly. However, SD of differences between comparative readings for SBP slightly decreased, whereas it increased for DBP readings. This is also visible in the total number of readings with differences ≤ 5 mmHg, which increased by one to 93 out of 99 for SBP and decreased by two to 91 out of 99 for DBP. Figure 2 illustrates the Bland-Altman plots of device - observer disagreements for the deflation measurement method. Similar to the inflation measurement method, the majority of results are valuated below 5 mmHg. Again, a dependency of the accuracy to the pressure level is not visible.

Table 1: Screening and recruitment details

Screening and recruitment			**Recruitment ranges**				
Total screened		47			mmHg	All	On Rx
Total excluded		14		Low	<90	0	
Ranges complete	11				90-129	12	0
Range adjustment	1		SBP	Medium	130-160	11	0
Arrhythmias	0			High	161-180	10	0
Device failure	0				>180	0	
Poor quality sounds	0						
Cuff size unavailable	0			Low	<40	0	
Observer disagreement	0				40-79	12	0
Distribution	2		DBP	Medium	80-100	11	0
Other reasons[a]	0			High	101-130	10	0
Total recruited		33			>130	0	

Abbreviations: SBP – Systolic blood pressure, DBP – Diastolic blood pressure, Rx – Antihypertensive drug prescription

Table 2: Subject details

Sex		
Male:Female	10:23	
Age (years)		
Range (Low:High)	25:82	
Mean (SD)	40.1 (13.1)	
Arm circumference (cm)		
Range (Low:High)	22:40	
Mean (SD)	30.9 (5.2)	
Cuff for test device		
Small	5	(17-26 cm)
Standard	16	(24-32 cm)
Large	10	(32-42 cm)
Extra Large	2	(38-46 cm)

	SBP (mmHg)	**DBP (mmHg)**
Recruitment (BPA)		
Range (Low:High)	96:177	56:120
Mean (SD)	139.3 (25.7)	87.1 (19.8)

Abbreviations: SBP – Systolic blood pressure, DBP – Diastolic blood pressure, SD – Standard deviation

Table 3: Observer measurements in each recruitment range

SBP (mmHg)	Inflation Mesurement Method	Deflation Measurement Method
Overall range (Low:High)	91:183	91:183
Low (<130)	43	43
Medium (130-160)	29	29
High (>160)	27	27
Maximum difference	16	16
DBP (mmHg)		
Overall range (Low:High)	49:120	49:120
Low (<80)	41	42
Medium (80-100)	35	34
High (>100)	23	23
Maximum difference	18	19

Abbreviations: SBP – Systolic blood pressure, DBP – Diastolic blood pressure

Table 4: Observer differences

	SBP (mmHg)	DBP (mmHg)	Repeated Measurements
Observer 2 – Observer 1			
Range (Low:High)	-4:4	-4:4	
Mean (SD)	0.4 (1.5)	0.3 (1.7)	4

Abbreviations: SBP – Systolic blood pressure, DBP – Diastolic blood pressure, SD – Standard deviation

Table 5: Validation Results (Part 1)

	≤ 5mmHg	≤ 10mmHg	≤ 15mmHg	Grade 1	Mean (mmHg)	SD (mmHg)
Pass Requirements						
Two of	73	87	96			
All of	65	81	93			
Achieved						
Inflation Measurement Method						
SBP	92	97	98	Pass	-0.1	3.6
DBP	94	99	99	Pass	0.5	2.4
Deflation Measurement Method						
SBP	93	98	99	Pass	0.2	2.8
DBP	91	98	99	Pass	0.1	2.9

Abbreviations: SBP – Systolic blood pressure, DBP – Diastolic blood pressure, SD – Standard deviation

Table 6: Validation Results (Part 2)

	2/3 ≤ 5mmHg	0/3 ≤ 15mmHg	Grade 2	Grade 3
Pass Requirements	≥ 24	≤ 3		
Achieved				
Inflation Measurement Method				
SBP	33	0	Pass	Pass
DBP	33	0	Pass	Pass
Deflation Measurement Method				
SBP	33	0	Pass	Pass
DBP	32	0	Pass	Pass

Abbreviations: SBP – Systolic blood pressure, DBP – Diastolic blood pressure, SD – Standard deviation

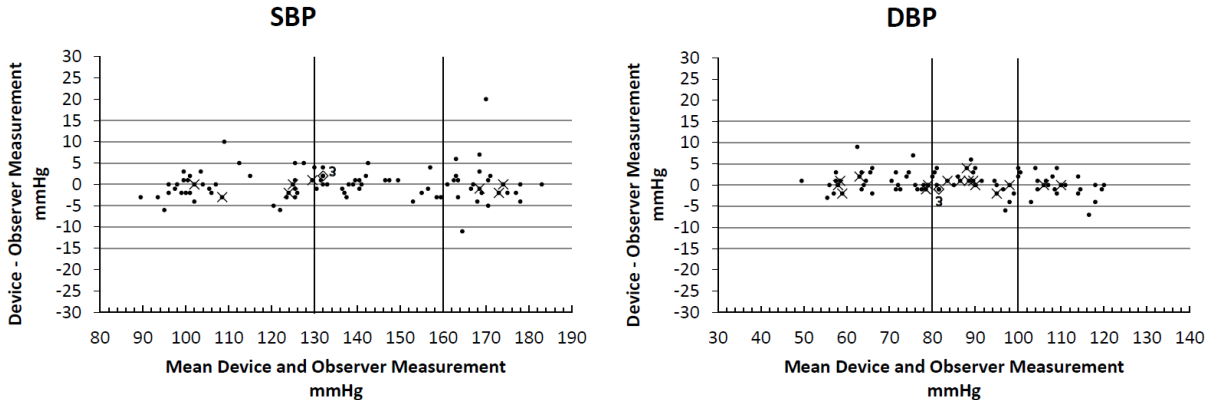

Figure 1: Bland-Altman plots of the differences between BP readings obtained with the inflation measurement method of the TONOPORT VI and reference measurements with a standard mercury sphygmomanometer, separate for systolic blood pressure (SBP) and diastolic blood pressure (DBP). Superimposed dots are displayed by X (one dot superimposed) or by ◊ (multiple dots superimposed - a number displays the total amount of dots at that position).

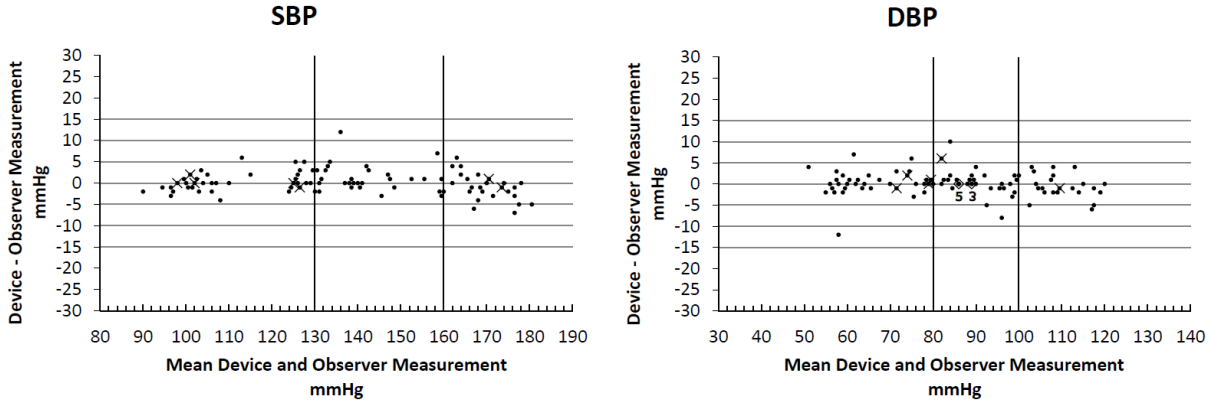

Figure 2: Bland-Altman plots of the differences between BP readings obtained with the deflation measurement method of the TONOPORT VI and reference measurements with a standard mercury sphygmomanometer, separate for systolic blood pressure (SBP) and diastolic blood pressure (DBP). Superimposed dots are displayed by X (one dot superimposed) or by ◊ (multiple dots superimposed - a number displays the total amount of dots at that position).

Discussion

Recruitment of subjects within the high BP range turned out difficult, which accounted for most of the excluded subjects. They were marked “range complete” and listed in Table 1. Two subjects had to be rejected even though their recruitment BP was within the high BP range, because the subsequent observer measurements drifted below the threshold. They were marked “distribution” and also listed in Table 1. Further drifts resulted in a lower measurement number in the high BP range, which can be observed in both SBP and DBP

plot. Nevertheless, all conditions regarding range, distribution, age, sex and size were fulfilled. The device offers two different measurement methods, which were both validated. Therefore, both methods were executed subsequently in the device readings. This is valid, since the overall measurement time was not increased by this procedure. The results illustrate a very good agreement, between observer and device measurements for both observed measurement methods. The device passed all criteria of the European Society of Hypertension International Protocol revision 2010, by far.

Conclusion

The TONOPORT VI ambulatory blood pressure measuring device passed all criteria of the European Society of Hypertension International Protocol revision 2010. This accounts to the newly developed inflation measurement method and to the conventional deflation measurement method. Therefore, the TONOPORT VI is recommended for blood pressure measurements in adults.

Acknowledgements and conflicts of interest

For this study, a TONOPORT VI was supplied by PAR Medizintechnik & Co. KG from Berlin, who also funded the study. None of the authors, nor the study personnel have any association with PAR Medizintechnik & Co. KG. Also, none of them received any personal benefit.

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