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Evaluation of Aktiia cuffless blood pressure monitor across 24-h, daytime, and night-time measurements versus ambulatory monitoring: a prospective, single-centre observational study

Tiago P. Almeida[a], David Perruchoud[a], Jérémy Alexandre[a], Pascale Vermare[a], Josep Sola[a], Jay Shah[a], Luisa Marques[b], and Cyril Pellaton[b]

Objectives: Cuffless blood pressure (BP) monitors represent an innovative approach to BP assessment, overcoming the traditional episodic nature of readings obtained from cuff-based, oscillometric modalities. Nonetheless, the comparison of these cuffless devices against their cuff-based counterparts remain debated.

Methods: This study evaluated BP readings from a cuffless, continual BP monitor (Aktiia monitor, Neuchatel, Switzerland) and a standard 24-h ambulatory BP monitor (ABPM; Dyasis 3, Novacor, Paris, France) in 54 patients undergoing a 12-week cardiac rehabilitation program in Neuchatel, Switzerland. Comparisons encompassed 24-h, daytime (9 a.m.–9 p.m.), and night-time (11 p.m.–7 a.m.) systolic and diastolic BP (SBP, DBP) using a 7-day average from Aktiia overlapping a 1-day average from ABPM. Nocturnal dip analysis was performed with 1-day average from Aktiia coinciding with ABPM measurements.

Results: No significant differences emerged between the Aktiia and ABPM monitors for 24-h and daytime SBP (24-h: $\mu \pm \sigma[95\%CI]$ 2.6 ± 12.3 [-0.2, 5.4] mmHg, $r = 0.57$, $P = 0.06$; daytime: 1.2 ± 12.4 [−1.6, 4.0] mmHg, $r = 0.60$, $P = 0.38$). Night-time SBP showed more evident differences (12.5 ± 14.4 [9.3, 15.8] mmHg, $r = 0.39$, $P < 0.001$). DBP were within clinical range across 24-h and daytime (24-h: -2.9 ± 7.9 [−4.7, −1.1] mmHg, $r = 0.63$, $P = 0.002$; daytime: -3.1 ± 8.2 [−5.0, −1.3] mmHg, $r = 0.64$, $P = 0.001$), and showed significant differences for night-time (4.1 ± 8.5 [2.2, 6.0] mmHg, $r = 0.57$, $P < 0.001$). The concordance rate with ABPM's nocturnal dip was 79% for 1-day average from Aktiia.

Conclusions: These results demonstrate that the Aktiia monitor yields BP measurements consistent with an ABPM monitor despite some systematic differences during night-time readings. The Aktiia monitor holds potential for future use in continual BP monitoring.

Clinical Trial Registration: NCT04548986. URL: https://clinicaltrials.gov/study/NCT04548986?tab=results

Graphical abstract: http://links.lww.com/HJH/C635

Keywords: ambulatory blood pressure monitor, continual blood pressure monitoring, cuffless blood pressure, hypertension, night dip blood pressure, optical blood pressure monitor

Abbreviations: ABPM, ambulatory blood pressure monitor; AUC, area under the curve; BP, blood pressure; CI, confidence interval; CR, cardiac rehabilitation; DBP, diastolic blood pressure; FQP, four-quadrant plot; HBPM, home blood pressure monitor; HR, heart rate; PPG, photoplethysmographic; ROC, receiver operating characteristic curve; ROI, regions ofiInterest; SBP, systolic blood pressure

INTRODUCTION

The diagnosis of hypertension primarily depends on cuff-based sphygmomanometers for blood pressure (BP) measurement. Accordingly, clinic BP assessments are limited to occasional daytime readings and are vulnerable to white-coat effects [1]. Home BP monitoring (HBPM) also focuses on daytime readings, but allows for long-term monitoring at home using automated, cuff-based oscillometric devices [1–3]. Finally, ambulatory BP monitoring (ABPM) provides a more extensive assessment by capturing 24–48-h BP snapshots with similar devices [1–3].

Recent studies demonstrated that 24-h BP measurements, particularly nocturnal readings and dipping patterns, more accurately predict all-cause mortality and cardiovascular events compared to clinic measurements [4–6]. These findings motivate wider use of ABPM. Nonetheless, patient adherence to cuff-based devices is notably low, mainly due to the discomfort associated with the cuff-based devices [7]. Despite debate about ABPM replacing

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[a]Aktiia SA and [b]Division of Cardiology, Réseau Hospitalier Neuchatelois (RHNe), Neuchatel, Switzerland

Correspondence to Tiago P. Almeida, Aktiia SA, Rue du Bassin 8a, 2000 Neuchatel, Switzerland. E-mail: publication@aktiia.com

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clinic BP monitoring [2], there is an urgent need for new BP modalities that provide measurements comparable to those of cuff-based devices but with improved comfort for long-term, continual monitoring.

Latest technological advancements have led to the development of several commercially available devices that measure BP without the need for an oscillometric cuff. These new solutions address the fundamental limitations of cuff-based monitors, with some designed for spot-check monitoring – similar to HBPM schedules – and others enabling continual long-term monitoring – similar to ABPM protocols [8]. However, recent data have highlighted the challenges these devices face in detecting BP nocturnal dip, even though they produce similar 24-h and daytime readings compared to ABPM [9]. Further research is needed to assess the performance of cuffless monitors in relation to ABPM.

In the present prospective, single-centre observational study, we compared 24-h, daytime, and night-time BP measurements performed by a cuffless BP monitor *versus* traditional ABPM. This represents results from the clinical trial NCT04548986 [10].

METHODS

Study population

A total of 63 patients (age 53.1 ± 7.2 years, 21.2% female, arm circumference 29.0 ± 2.5 cm, weight 81.8 ± 14.0 kg, height 174.1 ± 8.6 cm) were enrolled in a 12-week cardiac rehabilitation (CR) program (Réseau Hospitalier Neuchâtelois, Neuchâtel, Switzerland) following myocardial infarction or heart surgery. From the 63 recruited patients, 9 were excluded of the study (7 withdraws, 1 unintended event, 1 issue with the devices). The characteristics of the remaining 54 patients included in the study are detailed in Table S1, Supplementary Materials, http://links.lww.com/HJH/C636. The patients used a cuffless BP monitor (Aktiia monitor, Aktiia SA, Neuchâtel, Switzerland) during the 12 weeks of the CR program, while 24-h ABPM (Dyasis 3, Novacor, Paris, France) was performed twice – on the first and last day of the CR program (Figure S1A in the Supplementary Materials, http://links.lww.com/HJH/C636).

The clinical trial was approved by local ethics committee and all patients provided written informed consent.

The cuffless BP monitor

Aktiia SA (Aktiia, Neuchâtel, Switzerland) has developed a CE-marked, noninvasive, cuffless BP monitor that measures BP data following an initialization process using an oscillometric BP device [11,12]. Optical sensors embedded in a small bracelet collect photoplethysmography (PPG) signals acquired on the user's wrist. Following the initialization process, pulse wave analysis is applied to the photoplethysmographic (PPG) signals to estimate BP data, which is displayed in a smartphone application. This fully automated device generates no discomfort nor inconvenience for the patient, which makes the Aktiia monitor ideal for long-term continual BP monitoring in daily conditions.

Cuffless BP monitor initializations

Details on the initialization proceeding are published elsewhere [13]. Briefly, the clinical trials performed with the Aktiia monitor have shown that the initialization is reliable for 1 month and, therefore, it is the recommendation from Aktiia that initialization should be conducted at least once a month [14]. During the first session (the first week of CR), the initialization of the Aktiia monitor was performed on Day 1 for all subjects, that is, on the same day of the ABPM measurements. Since the CR program lasted for 12 weeks, multiple initialization (recalibrations) were performed by the subjects during this period after the first initialization performed on Day 1. As a result, the timing of these initializations for the second session (last week of CR) varied by individual. A visual representation of the measurements performed by each modality – and Aktiia's initializations – for each patient during the CR program is provided in the Supplementary Materials, http://links.lww.com/HJH/C636. Of the 63 patients enrolled in the 12-week CR program, 54 were included in the analysis, and 51 had valid measurements across the sessions (44 patients contributing to session 1 and 35 patients to session 2). To ensure conformity, measurements performed by the Aktiia monitor during the second sessions were always within 30 days of the latest initialization, as defined by Aktiia's regulatory requirements [14]. Additionally, patients were encouraged to perform a initialization immediately before starting an ABPM session, but initializations were not performed while ABPM sessions were ongoing.

It is important to note that the initialization process generates an offset in the BP measurements, but it does not influence the device's ability to track BP trends. These are distinct functionalities of the Aktiia monitor. Accordingly, prior to any initialization, the device captures the natural variability in BP, but without an absolute reference. The initialization simply provides a reference baseline for the BP readings, which continue to vary around this baseline. The subsequent initializations update the baseline without affecting the device's capacity to track BP changes over time.

Analysis for 1-day ABPM and 7-day Aktiia monitor

Average 24-h, daytime (9am-9pm) and night-time (11 p.m.−7a .m.) systolic and diastolic BP (SBP, DBP) and heart rate (HR) were calculated for 1-day ABPM and for 7-day Aktiia monitor, at the beginning and at the end of the CR program. The 7-day average for the Aktiia monitor provides a comprehensive representation of BP for one week in the lives of the patients.

For each patient and each time schedule (24-h, daytime and night-time), measurements were organised in two sessions of paired data. The first session consisted of the ABPM collected on the first day of CR compared with the data collected by Aktiia monitor on the first week of CR. Similarly, the second session consisted of the ABPM data collected on the last day of CR compared with the data collected by Aktiia monitor on the last week of CR.

Sessions were included in the analysis only if they had at least 20 valid daytime and 7 valid night-time ABPM measurements, in line with recent guidelines [15]. For the Aktiia monitor, an adapted compliance criterion required a minimum of 20 valid daytime measurements (with at least one measurement per day) and 7 valid night-time

measurements (with at least one per night) across one week for study inclusion.

Nocturnal dipping was assessed by comparing average daytime (9am-9pm) and night-time (11pm-7am) SBP and DBP measurements.

Night dip analysis for 1-day of ABPM coinciding with 1-day of Aktiia monitor

Average daytime (9 a.m.−9 p.m.) and night-time (11 p.m.−7 a.m.) SBP and DBP were calculated for 1-day ABPM coinciding with 1-day Aktiia monitor, at the beginning and at the end of the CR program. For each patient, measurements were organized in two sessions of paired data. In this case, session 1 compared first day's ABPM and Aktiia data; session 2 compared final day's readings from both devices. Only sessions with ≥20 daytime and ≥7 night-time measurements for ABPM, and ≥12 daytime and ≥8 night-time measurements for Aktiia were considered for analysis. Nocturnal dipping was assessed by comparing average daytime (9am-9pm) and night-time (11 p.m.−7 a.m.) SBP and DBP measurements.

The performance of the Aktiia monitor for night dipping identification was evaluated on SBP only as the area under the curve (AUC) of a receiver operating characteristic (ROC) curve considering -10% as the reference for ABPM night dip, and as the concordance rate (accuracy) of a four-quadrant plot (FQP). A ±6% exclusion zone around the ABPM dipping reference (−10%) was adopted to account for cuff variability.

Statistical analysis

A sample size of at least 60 sessions was determined as necessary to adequately assess the equivalence of 24-h ABPM values when compared to those obtained from the cuffless monitor. This sample size was calculated to ensure sufficient power to detect meaningful differences and establish robust conclusions regarding the performance of the two monitoring modalities.

The results of the BP comparisons are expressed as mean ± standard deviation ($\mu \pm \sigma$) and 95% confidence interval (CI) of BP differences, in addition to Student's paired *t*-tests. Population-level differences in BP measurements between Aktiia monitor and ABPM were investigated with scatter plots and Pearson correlation (r). Similarly, Bland−Altman plots were created to investigate individual-level measurements. Regions of interest (ROI) within ±10 mmHg and ±15 mmHg were included to assess levels of agreement [16].

P-values of <0.05 were considered statistically significant.

Independent data access and analysis

T.P.A., D.P., J. Sola and C.P. had full access to all the data in the study and take responsibility for its integrity and the data analysis.

RESULTS

Analysis for 1-day ABPM and 7-day Aktiia monitor

The 54 patients resulted in 108 sessions, out of which 79 sessions (73%) from 51 patients had valid measurements on the ABPM (24-h: 51 ± 5 readings; daytime: 34 ± 4; night-time: 8 ± 1) and on the Aktiia monitor (24-h: 236 ± 118 readings; daytime: 82 ± 55; night-time: 110 ± 51). Histograms of the number of readings per time schedule have been included in the Supplementary Materials, http://links.lww.com/HJH/C636. The average SBP values per hour for 1-day ABPM and 7-day Aktiia is illustrated in Figure S1B in the Supplementary Materials, http://links.lww.com/HJH/C636, with evident nocturnal dipping (11 p.m.−7 a.m.) on both modalities.

The SBP and DBP averages for the different time schedules and their respective nocturnal dipping (both in absolute and percentual values) measured with 7-day average Aktiia and 1-day average ABPM are shown in Table 1. The differences between the modalities are also displayed.

Results for the 24-h schedule are illustrated in Fig. 1. No significant differences were found for SBP (Fig. 1a, $\mu \pm \sigma$ [95% CI]: 2.6 ± 12.3 [-0.2, 5.4] mmHg, $P = 0.06$; $r = 0.57$). The two modalities resulted in agreements of 57% and 79% within the ±10 mmHg and the ±15 mmHg ROI, respectively. Significant bias – but within clinical acceptance of ±8 mmHg variance – was found between Aktiia monitor and ABPM for DBP (Fig. 1b, −2.9 ± 7.9 [−4.7, v1.1] mmHg, $P = 0.002$; $r = 0.63$), with agreements of 78% and 94% within the ±10/±15 mmHg ROI, respectively. HR (Fig. 1c) was significantly lower for Aktiia monitor measurements compared to ABPM (−10.5 ± 6.5 [−12.0, −9.1] mmHg, $P < 0.0001$; $r = 0.65$).

TABLE 1. 24-h, daytime and night-time BP values measured with 7-day average Aktiia and 1-day average ABPM, and the differences between the two modalities for 79 sessions from 51 users

	Aktiia 7-day average	ABPM 1-day average	Difference ± SD [95% CI]	P-value
Systolic BP (mmHg)				
24-h	110 ± 14	108 ± 12	2.6 ± 12.3 [-0.2, 5.4]	0.06
Daytime	112 ± 15	111 ± 13	1.2 ± 12.4 [-1.6, 4.0]	0.38
Nocturnal	109 ± 14	97 ± 12	12.5 ± 14.4 [9.3, 15.8]	<0.001
Nocturnal dip	-2.5 ± 3.0	-13.8 ± 10.1	11.3 ± 10.2 [9.0, 13.6]	<0.001
Nocturnal dip (%)	-2.1 ± 2.7	-12.2 ± 8.6	10.1 ± 8.9 [8.1, 12.1]	<0.001
Diastolic BP (mmHg)				
24-h	67 ± 9	69 ± 10	-2.9 ± 7.9 [-4.7, -1.1]	0.002
Daytime	68 ± 9	71 ± 10	-3.1 ± 8.2 [-5.0, -1.3]	0.001
Nocturnal	66 ± 9	61 ± 10	4.1 ± 8.5 [2.2, 6.0]	<0.001
Nocturnal dip	-2.6 ± 2.4	-9.9 ± 6.6	7.2 ± 6.9 [5.7, 8.8]	<0.001
Nocturnal dip (%)	-3.8 ± 3.5	-13.7 ± 8.8	9.9 ± 9.3 [7.8, 12.0]	<0.001

Values expressed as $\mu \pm \sigma$.

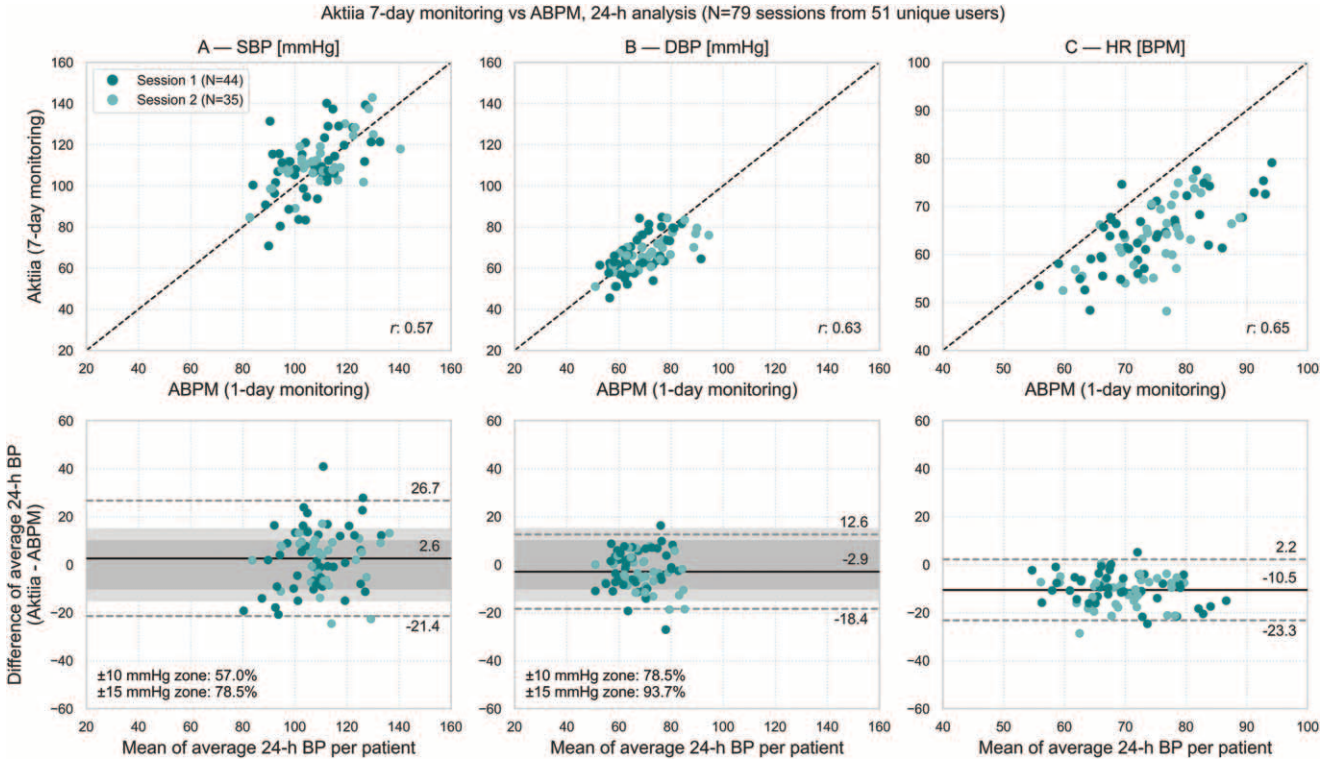


FIGURE 1 Scatter plots (upper) and Bland-Altman plots (bottom) comparing 24-h BP measurements performed by Aktiia monitor (7-day average) and ABPM (1-day average). **A.** Comparison of 24-h SBP. **B.** Comparison of 24-h DBP. **C.** Comparison of 24-h HR. Pearson's correlation (r) between the two modalities is shown on the bottom right of the scatter plots. ROI within ± 10 mmHg and ± 15 mmHg are highlighted in dark grey and light grey, respectively. The percentage of agreement for each region is shown on the bottom left of the Bland-Altman plots. The solid black line denotes the average mean of differences, while the dotted lines denote the limits of agreement (±1.96σ). BPM – beats per minute.

Figure 2 shows the results for daytime schedule. No significant differences were found for SBP (Fig. 2a, 1.2 ± 12.4 [−1.6, 4.0] mmHg, $P = 0.38$; $r = 0.60$), with agreements of 58% and 80% within the ±10/±15 mmHg ROI, respectively. DBP also displayed bias within clinical acceptance between modalities for DBP (Fig. 2b, v3.1 ±8.2 [−5.0, −1.3] mmHg, $P = 0.002$; $r = 0.64$), with agreements of 77% and 94% within the ±10/±15 mmHg ROI, respectively. HR (Fig. 2c) was significantly lower for Aktiia monitor measurements compared to ABPM (−9.9 ± 7.6, CI: [−11.6, −8.2] mmHg, $P < 0.0001$; $r = 0.61$).

Finally, Fig. 3 illustrates nocturnal results. Significant differences were found for SBP (Fig. 3a, 12.5 ± 14.4 [9.3, 15.8] mmHg, $P < 0.001$; $r = 0.39$), with agreements of 42% and 56% within the ±10/±15 mmHg ROI, respectively. Significant bias was also found for DBP (Fig. 3b, 4.1 ± 8.5 [2.2, 6.0] mmHg, $P < 0.001$; $r = 0.57$), with agreements of 68% and 86% within the ±10/±15 mmHg ROI, respectively. HR (Fig. 3c) was significantly lower for Aktiia monitor measurements compared to ABPM (−4.4 ± 7.8, CI: [−6.2, −2.7] mmHg, $P < 0.0001$; $r = 0.68$).

Nocturnal dips for SBP and DBP were significantly different between the two modalities, on both absolute and percentual values (Table 1, $P < 0.0001$ in all cases).

Night dip analysis for 1-day of ABPM coinciding with 1-day of Aktiia monitor

A total of 38 valid sessions were identified from 30 patients with valid measurements on 1-day ABPM coinciding with 1-day Aktiia monitor (24-h: 52 ± 24 readings; daytime: 22 ± 12; night-time: 21 ± 12). Histograms of the number of readings per time schedule have been included in the Supplementary Materials, http://links.lww.com/HJH/C636. Analysis for 1-day ABPM coinciding with 1-day Aktiia monitor have also been included in the Supplementary Materials, http://links.lww.com/HJH/C636.

The ROC curve created to test the night dip identification by the Aktiia monitor, with the −10% SBP ABPM night dip as the reference, is shown in Fig. 4a. The night dip classification by the Aktiia monitor achieved an AUC of 0.72. The optimal operating point, defined as the point on the curve closest to the top left corner, was found at −2.96%. This resulted in a precision of 83.3%, sensitivity of 90.9%, and specificity of 62.5%. These results suggest that an adapted threshold of −2.96% should be considered for Aktiia to detect night dipping, based on the -10% ABPM dipping classification. Furthermore, as illustrated in Fig. 4b, using the newly determined threshold of −2.96%, the Aktiia monitor accurately identified 78.9% of the nocturnal dips defined by the −10% ABPM dipping classification.

DISCUSSION

In the present prospective, single-centre observational study, we evaluated 24-h, daytime, and night-time BP measurements performed by a commercially available cuffless BP monitor compared to a traditional 24-h ABPM. The results demonstrate that the cuffless monitor yields BP measurements consistent with ABPM during 24-h and

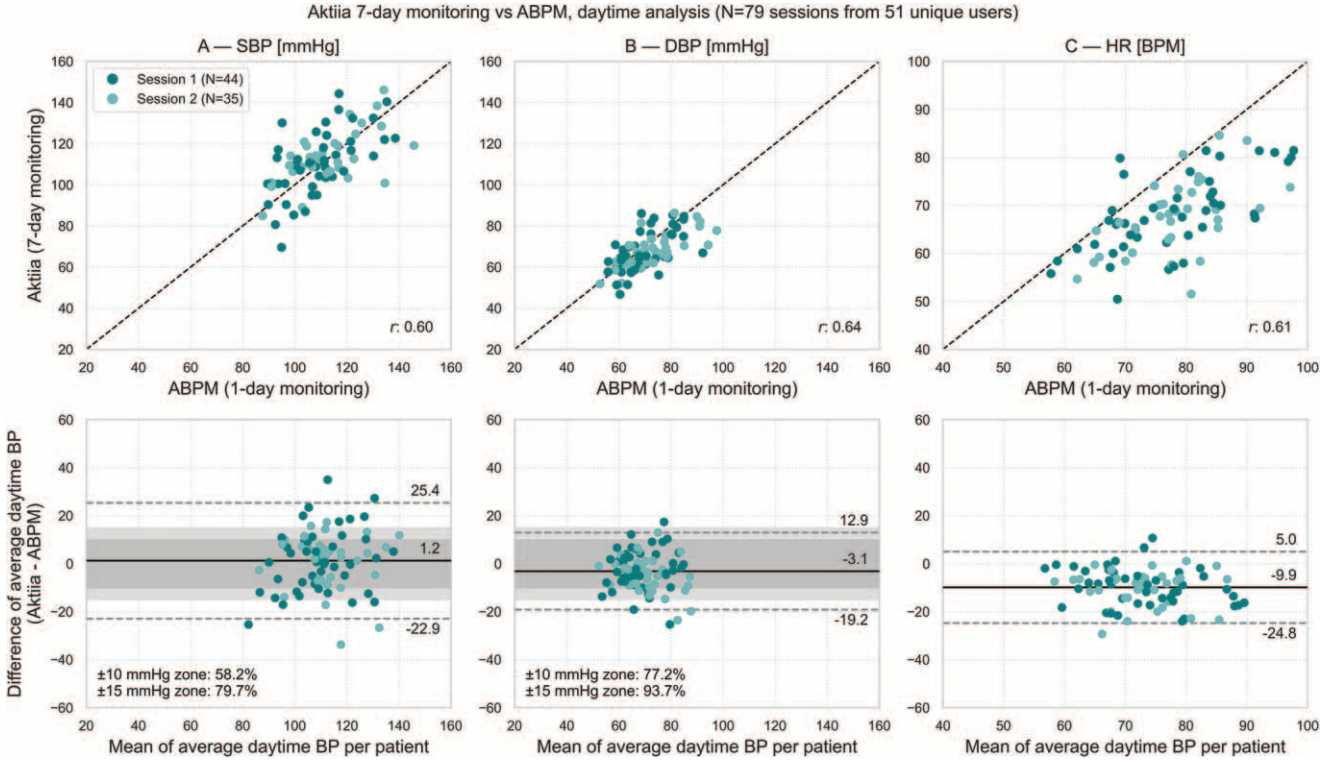


FIGURE 2 Scatter plots (upper) and Bland-Altman plots (bottom) comparing daytime BP measurements performed by Aktiia monitor (7-day average) and ABPM (1-day average). **A.** Comparison of daytime SBP. **B.** Comparison of daytime DBP. **C.** Comparison of daytime HR. Pearson's correlation (r) between the two modalities is shown on the bottom right of the scatter plots. ROI within ± 10 mmHg and ± 15 mmHg are highlighted in dark grey and light grey, respectively. The percentage of agreement for each region is shown on the bottom left of the Bland-Altman plots. The solid black line denotes the average mean of differences, while the dotted lines denote the limits of agreement (±1.96σ). BPM – beats per minute.

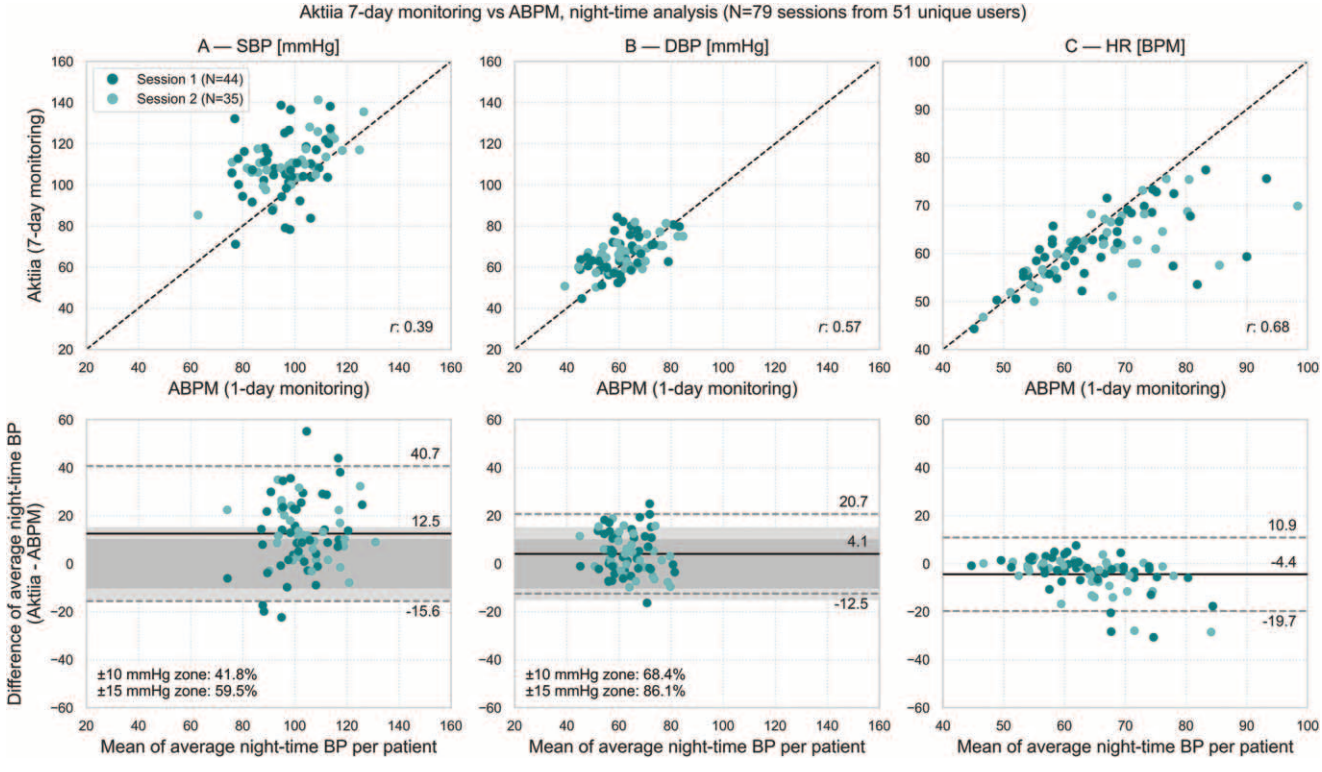


FIGURE 3 Scatter plots (upper) and Bland-Altman plots (bottom) comparing night-time BP measurements performed by Aktiia monitor (7-day average) and ABPM (1-day average). **A.** Comparison of night-time SBP. **B.** Comparison of night-time DBP. **C.** Comparison of night-time HR. Pearson's correlation (r) between the two modalities is shown on the bottom right of the scatter plots. ROI within ± 10 mmHg and ± 15 mmHg are highlighted in dark grey and light grey, respectively. The percentage of agreement for each region is shown on the bottom left of the Bland-Altman plots. The solid black line denotes the average mean of differences, while the dotted lines denote the limits of agreement (±1.96σ). BPM – beats per minute.

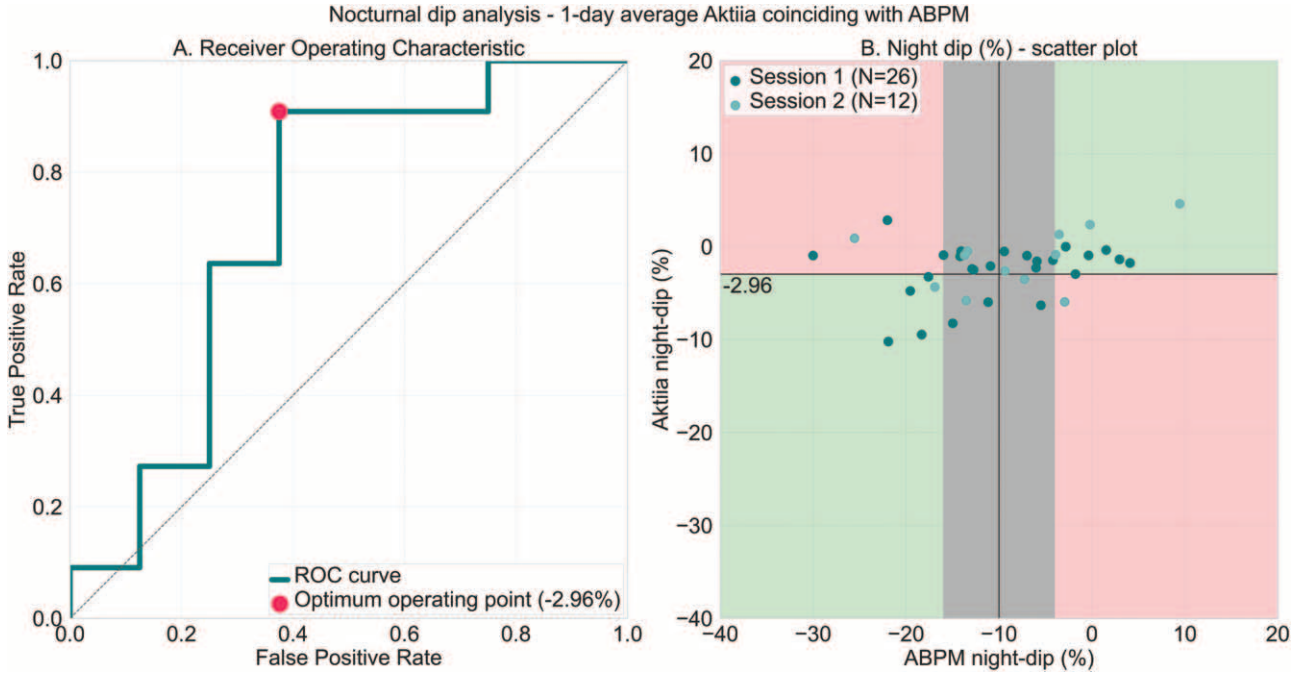


FIGURE 4 The performance of SBP night dipping identification by the Aktiia monitor considering -10% as the reference for ABPM night dip and a ± 6% exclusion zone around the ABPM dipping reference. **A.** The ROC curve created to test night dip detection by the Aktiia monitor, with an AUC of 0.72 and optimal operating point at -2.96% (red dot, 91% sensitivity, 63% specificity). **B.** Four-quadrant plot (FQP) comparing the nocturnal dips detected by the Aktiia monitor and ABPM, with a CR of 78.9% (83.3% precision).

daytime schedules. Additionally, despite some systematic differences during night-time readings, the cuffless monitor effectively tracked nocturnal dipping in line with ABPM.

24-Hour and daytime BP measurements with cuffless BP monitor

The present clinical trial has shown that one week of Aktiia monitoring compares well to 24-h of ABPM monitoring. Either no significant bias or bias within clinical acceptance were found between the two BP modalities on both 24-h and daytime averages for SBP and DBP, converging to agreements within ±15 mmHg close – or superior – to 80% [16–18].

For all time schedules (24-h, daytime and night-time measurements), the HR recorded by the Aktiia monitor was lower than that measured by the ABPM. This difference is due to the fact the Aktiia device captures PPG data only when the user's wrist remains stationary for 30-s, whereas ABPM performs measurements regardless of the user's physical activity, potentially leading to increased HR values. This suggests that the Aktiia monitor conducts measurements under more controlled conditions – specifically when the user is at rest. Furthermore, the Aktiia monitor takes HR measurements unobtrusively, in contrast to the ABPM, which measures HR during upper-arm cuff inflation. This often causes discomfort and may inadvertently raise the individual's HR, contributing to the lower HR readings observed with the Aktiia monitor – also during the night.

Night-time BP measurements and nocturnal dip with cuffless BP monitor

A recent study has demonstrated the dominance of ABPM over clinic BP in the association between BP and cardiovascular and all-cause mortality [4]. In particular, nondipping patterns have been associated with long-term nonfatal cardiovascular events [5,6]. These results highlight the importance of introducing novel methods that allow long-term, continual, accurate BP monitoring for improved diagnostic.

Significant differences were found in nocturnal SBP and DBP measurements between the Aktiia monitor and ABPM, in line with recently published data [9]. The cuffless BP monitor consistently reported higher nocturnal BP values, which is also evident from the smaller nocturnal reductions recorded by Aktiia compared to ABPM. Nonetheless, the cuffless monitor successfully identified 79% of individuals classified as SBP dippers by ABPM. This result suggests that, while ABPM detects dipping patients with a threshold of -10%, Aktiia detects the same dipping patients, but with an adapted threshold of -2.96%. This was achieved with an adjusted threshold for dipping detection as indicated by the optimal operating point on the ROC curve, which is around -3% for the Aktiia monitor – approximately threefold less compared to the −10% threshold currently defined for ABPM [11].

As a comparative study, it is essential to recognize that if the metrics used in the analyses do not align perfectly, it does not inherently imply that the devices are unreliable for individual subjects. Instead, it suggests that the devices offer alternative characterizations of the same individuals, both of which contribute valuable information. Importantly, the Aktiia monitor and ABPM utilize distinct methods to measure BP, which naturally lead to variations in BP readings under various conditions [19]. Firstly, ABPM readings taken with oscillometric cuffs are influenced by hydrostatic and gravitational forces that change with the body's position

[20]. In contrast, the proprietary algorithm used in Aktiia devices has shown resilience to such positional changes [12]. Secondly, from a metrological standpoint, current validation protocols for oscillometric cuffs do not evaluate their performance on different body positions, particularly when the subject is lying down during sleep [17]. Consequently, while recent data underscored the importance of BP monitoring with ABPM [4], it is essential to interpret oscillometric cuff data with caution when obtained in positions other than sitting. In comparison, Aktiia has shown consistent BP measurements across various body positions, including supine, when compared to auscultatory BP readings [12].

Clinical impact and the future of BP monitoring

The field of hypertension management is undergoing a revolutionary shift with the advent of cuffless BP measurement technologies. Despite decades of efforts, current hypertension management strategies – such as those involving ABPM – achieved global control rates around 20% [21]. There has been intense debate on recent advances in cuffless BP devices [9,19,22–24], highlighting the necessity for comprehensive evaluations in both clinical and research environments. The Aktiia monitor, in particular, has shown promising results, providing BP measurements comparable to 24-h ABPM over a week-long period. This achievement underscores its potential as a tool in hypertension care, provided that patient adherence is maintained. The ability to gather extensive BP data without the discomfort associated with traditional cuff-based methods is a game-changer. It facilitates widespread adoption and drive better patient compliance, providing healthcare providers with unprecedented data density over extended periods. This wealth of data facilitates more accurate BP profile delineation and offers new opportunities for personalized patient care. Moreover, Aktiia's capability to effectively track nocturnal dipping, despite systematic differences in nighttime readings, highlights the potential for improving cardiovascular risk assessments. While our results are confined to our study's demographic [10], we suggest a new paradigm in BP evaluation – moving beyond sporadic measurements or even 24-h monitoring to a model that prioritizes patient comfort and continual BP management over extended periods.

We believe that adopting a new approach based on cuffless monitoring, which frequently updates and refines BP data through an engaging, patient-centred methodology, could significantly enhance hypertension management outcomes. These groundbreaking innovations adhere to rigorous scientific standards, promote global accessibility, and enhance patient engagement and convenience, enabling more patient-centric, long-term, automated, noninvasive, and continual BP monitoring that could transform the way hypertension is diagnosed and managed globally.

Future research should focus on minimizing discrepancies and enhance the accuracy of nocturnal BP measurements. As these technologies evolve, their integration into routine clinical practice could transform hypertension management by prioritizing patient comfort and providing BP management over long durations.

Limitations

The patients underwent cardiovascular events (myocardial infarction, heart surgery) prior to CR. All patients were treated at the time of inclusion, leading to mostly normotensive patients analysed in this study.

The current analysis included only patients that presented 7 days of continual data collection with Aktiia monitor. The implementation of the exact setup in real-life monitoring conditions might require some patients to wear the Aktiia monitor for longer in order to obtain enough measurements.

This study was not designed to assess the effect of the CR program on BP. Specifically, BP change or control was not an endpoint of the CR program, and the study did not aim to track BP changes attributable to CR. Accordingly, BP changes observed post-CR were marginal, and mostly not statistically significant. Therefore, due to the design of the study, our primary focus was on comparing how BP readings evolve throughout the day across the two modalities. Previous findings suggest that while the BP changes captured by Aktiia correlate with ABPM readings, the changes tend to be smaller in magnitude (approximately threefold for nocturnal data) [11]. The current study supports this observation.

Ultimately, since this is an observational study where the effect of the CR program on BP values is not tested, the two 24-h ABPM sessions were chosen as they offer an adequate representation of current clinical guidelines, which focus primarily on 24-h monitoring periods. We adapted a CR program that already existed to collect this observational data. And since the program already included 2 ABPM exams per patient, both were included in the analysis. We believe, therefore, this approach sufficiently supports the comparative methodology and conclusions of our study.

CONCLUSIONS

In the present prospective, single-centre observational work, the Aktiia monitor demonstrated the ability to provide BP measurements comparable to those from 24-h ABPM over a week-long period, endorsing its suitability for ongoing, continual BP monitoring. Provided that patients adhere sufficiently, the Aktiia monitor could potentially replace ABPM. Notably, the enhanced usability and comfort of the Aktiia monitor may lead to better patient compliance and broader adoption. This ease of use allows clinicians to access critical BP data over extended periods, essential for the accurate diagnosis and management of hypertension. Additionally, despite systematic differences in nocturnal BP values, night-time dipping can be tracked with the Aktiia monitor considering the adjusted threshold for dipping detection.

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Data availability statement: The data that support the findings of this study can be made available by Aktiia SA. However, restrictions apply to the availability of these data,

which were used under license for the current study, and so are not publicly available. Therefore, availability of such data may be limited, and any access, if permissible, is subject not only to a justifiable request to be approved by Aktiia, but also to specific terms and conditions to be agreed.

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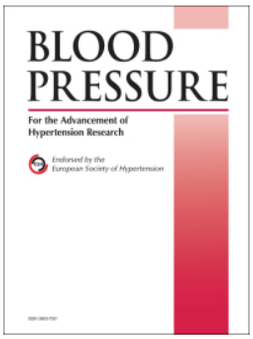
Almeida TP, Perruchoud D, Alexandre J, Vermare P, Sola J, Shah J, *et al*. Tracking nocturnal blood pressure dipping with the Aktiia cuffless monitor. Journal of Hypertension 2024;42:e73–4. https://doi.org/10.1097/01.hjh.0001019980.91229.85.

Conflicts of interest

T.P.A., D.P., P.V., J.S. and J.S. are employees of Aktiia SA. All other authors report no potential conflicts of interest.

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RESEARCH ARTICLE

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Performance of the Aktiia optical blood pressure measurement device in the elderly: a comparison with double blinded auscultation in different body positions

Kenji Theiler[a], Josep Sola[b], Aikaterini Damianaki[a], Alexandre Pfister[b], Tiago P Almeida[b], Jérémy Alexandre[b], Pascale Vermare[b] and Gregoire Wuerzner[a]

[a]Service of Nephrology and Hypertension, Lausanne University Hospital and University of Lausanne, Lausanne, Switzerland; [b]Aktiia SA, Neuchâtel, Switzerland

ABSTRACT

Background:: Accurate blood pressure (BP) measurement is essential for the correct diagnosis and management of hypertension (HTN) especially in the elderly population. As with of all BP devices, the accuracy of cuffless devices must be verified. This study (NCT04027777) aimed to evaluate the performance of a wrist cuffless optical BP device in an elderly population cohort in different body positions with auscultation as the reference measurement.

Design and methods: Patients aged 65-85 years with different BP categories but without diabetes were recruited. After an initial calibration based on auscultatory measurements, BP estimation from the Aktiia Bracelet (Aktiia SA, Switzerland) were compared to reference double-blinded auscultatory measurements in sitting, standing and lying positions on four separate visits distributed over one month. In the absence of a universal standard for cuffless BP device at the time of the study, modified ISO81060-2 criteria were used for performance analysis.

Results: Thirty-five participants were included in the analysis fulfilling the inclusion requirements of ISO 81060-2. A total of 469 paired measurements were obtained with overall 83% acceptance rate. Differences (mean ± SD) between Aktiia Bracelet and auscultation for systolic BP were -0.26 ± 9.96 mmHg for all body positions aggregated (sitting 1.23 ± 7.88 mmHg, standing -1.81 ± 11.11 mmHg, lying -1.8 ± 9.96 mmHg). Similarly, differences for diastolic BP were -0.75 ± 7.0 mmHg (0.2 ± 5.55 mmHg, -5.35 ± 7.75 mmHg and -0.94 ± 7.47 mmHg, respectively). Standard deviation of the averaged differences per subject for systolic/diastolic BP was 3.8/2.5 mmHg in sitting and 4.4/3.7 mmHg for all body positions aggregated.

Conclusions: Overall, this study demonstrates a similar performance of the Aktiia Bracelet compared to auscultation in an elderly population in body positions representative of daily activities. The use of more comfortable, non-invasive, and non-occlusive BP monitors during long periods may facilitate e-health and may contribute to better management of HTN, including diagnosis and treatment of HTN, in the elderly.

PLAIN LANGUAGE SUMMARY

Accuracy of blood pressure measurements is essential in the diagnosis and the follow-up of patients with high blood pressure. As with any blood pressure measuring device, a validation is necessary. In this study including a elderly population, we compared values obtained by the cuffless Aktiia Bracelet (Aktiia SA, Switzerland) after an initial calibration with the reference auscultatory method during four separate study days distributed over one month. We show that the accuracy of the Aktiia Bracelet is similar to auscultation. The accuracy varies depending on the position in which the measurement is performed. Overall, the accuracy is not modified by a higher age category. The use of a cuffless device in the elderly population characterized by high prevalence of hypertension may facilitate the follow-up of blood pressure with more comfort and minimal constraints.

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elderly; cuffless; blood pressure measurement; auscultatory

Introduction

Arterial hypertension (HTN) is a silent disease affecting around 1.4 billion people worldwide in 2021 [1]. It is a major cardiovascular risk and is responsible for premature death, ischaemic heart disease and stroke [2]. Globally, almost half of the hypertensive patients

CONTACT Dr Gregoire Wuerzner, MD gregoire.wuerzner@chuv.ch Service de néphrologie et d'hypertension, CHUV Rue du Bugnon 17 1005 Lausanne Switzerland

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are unaware that they have the condition, and more than half of treated hypertensive are not controlled [1]. Thus, early diagnosis and cardiovascular risk stratification with accurate and precise blood pressure (BP) measurement is essential. This is especially true for the elderly population, the age category with the highest prevalence of HTN [3].

In recent years, wearable health-related devices have significantly gained in popularity. These devices have multiple advantages, such as persistent monitoring of clinical parameters, physical activity tracking, fall prevention and alert. However, the adoption of wearables is limited to 17.5% of elderly in the USA [4]. Cuffless BP monitoring is also gaining popularity in the field of wearable devices. However, there is currently an intense debate on the performance of cuffless BP monitors, and further validation is still needed prior to their use in clinical practice [5].

The Aktiia Bracelet (Aktiia SA, Neuchâtel, Switzerland) is a wearable CE-marked Class IIa medical device. This wrist cuffless non-invasive optical BP monitor (OBPM) has embedded sensors and operates on the principle of reflection photoplethysmography (PPG), capturing blood volume pulsatility. Pulse wave analysis is used to transform the recorded signal in BP values. Recent studies have shown a strong correlation between the Aktiia Bracelet and invasive BP measurements [6], and a strong correlation with double auscultation in a general population aged between 21 and 65 years in different body positions [7].

As the elderly population is considered as a special patient population in validation protocols, the aim of this study was to test the accuracy of the OBPM Aktiia Bracelet compared to double-blinded auscultation measurements in an elderly population cohort with levels of BP and in different body positions.

Material and methods

Ethical consent and study registration

The Local Ethics Committee (CER-VD—Commission cantonale d'éthique de la recherche sur l'être humain, CH 1012 Lausanne, Switzerland, authorization no. 2019-01046 of 06/08/2019) and the Swiss authority responsible for the authorization and supervision of therapeutic products (Swissmedic, CH-3012 Bern, Switzerland, authorization no. 10000542 of 29/07/2019) approved this study. The study was registered in EUDAMED (registration no. CIV-19-06-029004 of 29/07/2019) and ClinicalTrials.gov (registration no. NCT04027777 of 22/07/2019). It was conducted in accordance with the principles of the Declaration of Helsinki, the International Council for Harmonisation Good Clinical Practice guidelines, ISO 14155 and all applicable regulatory requirements. All the patients provided written informed consent.

Study population

Eligibility criteria included participants with age between 65 and 85 years, with fluent spoken French, who agreed to attend the totality of 4 visits within one month and who had signed the informed consent form. Exclusion criteria were: atrial fibrillation, a heart rate >120 beats/min, diabetes, estimated glomerular filtration rate (eGFR) <45 mL/min/1.73m^2, hyper-/hypothyroidism, pheochromocytoma, Raynaud's disease, arteriovenous fistula, interarm SBP difference over 15 mmHg or DBP difference >10 mmHg, arm paralysis; arm amputation, upper arm circumference >64 cm, wrist circumference >22 cm, central phalanx of the middle finger circumference >71 mm or <43 mm, exfoliative skin diseases and lymphoedema.

Participants with various range of BP ranging from low to high were included to meet ISO 81060-2 validation protocol standard. Participants were recruited from an outpatient hypertension clinic and via social media advertising. Antihypertensive treatment, if already prescribed, was maintained throughout the study, barring clinical necessity for alteration. Eligibility was assessed during a preliminary screening visit involving a review of medical records and a physical examination.

Experimental set-up

The study was conducted in the Service of nephrology and hypertension at the Lausanne University Hospital (CHUV) in Lausanne Switzerland. The protocol has been described previously [7]. Briefly, participants were investigated on day 1, and after 9 ± 3, 18 ± 3, and 29 ± 3 days in different body positions: sitting with de device at the heart level; sitting with the device on the lap; lying; and standing. Each change in body position was followed by 2.5 minutes rest to stabilize BP. The Aktiia bracelet was initialized/calibrated on the basis the first auscultatory measures of day 1 only. The Aktiia bracelet was located on the right wrist, finger volume clamp measurement (Nexfin BMYE, Netherlands), which was used to verify the accuracy of the reference auscultatory measurements at each body position change as previously described and pulse oximeter devices on the left side [7]. Double blinded auscultation was performed by two

experienced observers on the left arm. Therefore, BP was measure simultaneously by the Atkiia bracelet and the auscultatory technique according to IEEE Standard 1708a-2019 and ISO Standard 81060-3 (2022) [8]. Optical signal was recorded for 30 seconds, simultaneously to double auscultation identifying K1 and K5 Korotkoff sounds for the determination of systolic and diastolic BP (SBP, DBP), respectively.

Statistical analysis

Mean and standard deviation of the differences between SBP and DBP measurements provided by the Aktiia algorithm and reference mean double auscultation was calculated. Criterion 1 investigates population-level measurements, while criterion 2 investigates individual-level measurements. Accordingly, population-level differences in BP measurements between Aktiia monitor and auscultatory blood pressure were investigated with scatter plots and Pearson's correlation (r). Bland-Altman plots were created to investigate individual-level measurements. Regions of interest (ROI) within ±5/±10/±15 mmHg were included to assess levels of agreement [9]. The root mean square error (RMSE) was calculated for HR measurement performed by Aktiia and the reference method (oximetry). P-values of less than 0.05 were considered statistically significant.

Results

The study enrolled a total of 40 participants, but 5 participants were excluded from the analysis to meet the inclusion criteria of ISO 81060-2 (Figure 1). In this elderly population (N = 35, 46% women, 73 ± 6 years), most participants had normal or high BP. Detailed demographic characteristics and BP phenotypes for the 35 participants are available in table 1.

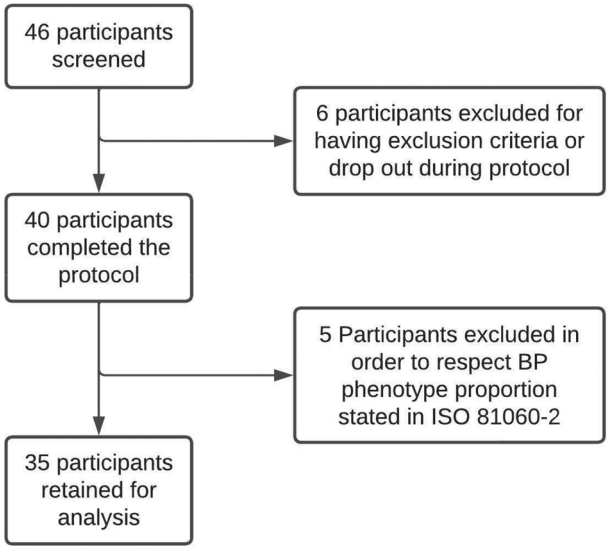


Figure 1. Study Flow chart.

A total of 468 of paired measurements were performed, 282 collected at rest. The acceptance rate at rest was 83%, with 235 paired measurements retained with sufficient optical signal quality – 175 at sitting position, 36 at lying position and 24 at standing position. These data were used in the subsequent parts of this investigation.

Table 2 shows the mean and standard deviation of the BP differences in each body position between double auscultation and the Aktiia Bracelet. The sitting position had the accuracy with the lowest mean error and the lowest standard deviation of this mean error compared to the auscultatory method at BP-reading-level.

For per subject analysis in criterion 2, measured standard deviation of the averaged differences in sitting was 3.8 and 2.5 mmHg for SBP and DBP respectively. For all body positions aggregated, we obtained 4.0/3.3 mmHg. For sitting, where the ISO81060-2 validation criteria would be applicable for oscillometric devices, the results obtained pass both criteria 1 and 2.

The correlation between the two techniques (auscultatory vs optical) was high overall, with the best correlation obtained in the sitting position. Figure 2, 3, 4 and 5 illustrates scatter plots and Bland-Altman plots for SBP and DBP for sitting, lying, standing and all positions, respectively.

Compared to oximetry, the root mean square errors of the heart rate for sitting, lying, standing and all body positions were, respectively, 3.51, 3.33, 3.93 and 3.53 beats/min.

Table 1. Demographic and clinical characteristics of the study population (N = 35).

Age, years*	72.8 ± 6.0 [65-85]
Sex, male/female	19/16 (54%/46%)
Arm circumference*, cm	26.3 ± 4.0 [16-35]
BMI*, kg/m^2	26.1 ± 4.6 [17.6-38.6]
Prevalence of obesity (BMI ≥ 30 kg/m^2)	5 (14.3%)
SBP*, mmHg	134.7 ± 14.8 [104-162]
≤100 mmHg	0 (0.0%)
≥140 mmHg	13 (37.1%)
≥160 mmHg	2 (5.7%)
DBP*, mmHg	77.5 ± 9.8 [61-105]
≤60 mmHg	0 (0.0%)
≥85 mmHg	6 (17.1%)
≥100 mmHg	1 (2.9%)
Pulse pressure*, mmHg	58.2 ± 14.7 [34-89]
Isolated Systolic Hypertension	10 (29%)
Skin category, Fitzpatrick scale	
1-2	29 (82.9%)
3-4	5 (14.3%)
5-6	1 (2.9%)
Forearm hair category, Schuckmann scale	
0-2	31 (88.6%)
3	4 (11.4%)

*Numbers represented as (mean ± SD) [range].

Table 2. Performance of the Aktiia Monitor when compared against double auscultation for different body positions. Results depict means and standard deviation of the differences between the two measuring modalities, and pass/fail criteria of ISO81060-2 when applicable.

			Analysis at BP-reading-level (ISO 81060-2 criterion 1)						Analysis at subject-level (ISO 81060-2 criterion 2)		
Body position	N readings	BP (mmHg)	Mean error	ISO Target	Result	SD	ISO Target	Result	SD of mean of differences	ISO Target	Result
Sitting	175	SBP	1.23	≤ ±5	**PASS**	7.88	≤8	**PASS**	3.78	≤6.84	PASS
		DBP	0.20		**PASS**	5.55		**PASS**	2.48	≤6.95	PASS
Lying	36	SBP	−4.27	N.A.	N.A.	9.84	N.A.	N.A.	6.09	N.A.	N.A.
		DBP	−1.51		N.A.	7.38		N.A.	6.25		N.A.
Standing	24	SBP	−4.66	N.A.	N.A.	9.64	N.A.	N.A.	6.26	N.A.	N.A.
		DBP	−6.06		N.A.	7.80		N.A.	6.82		N.A.
All	235	SBP	−0.21	N.A.	N.A.	8.72	N.A.	N.A.	4.00	N.A.	N.A.
		DBP	−0.74		N.A.	6.41		N.A.	3.34		N.A.

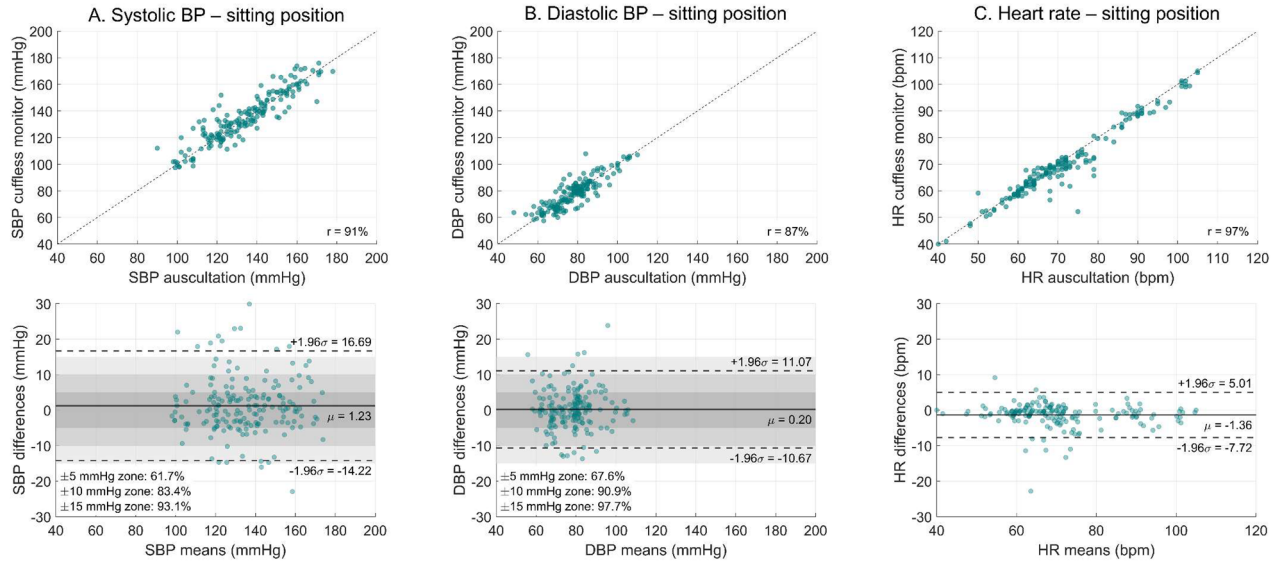


Figure 2. Scatter plots (upper) and Bland-Altman plots (bottom) comparing SBP (**A**) and DBP (**B**) measurements performed by Aktiia monitor and double auscultation for sitting position and comparing heart rate measurement by Aktiia monitor and pulse oximetry (**C**). Pearson's correlation (r) between the two modalities is shown on the bottom right of the scatter plots. ROI within ±5 mmHg, ±10 mmHg and ±15 mmHg are highlighted from darker to lighter, respectively. The percentage of agreement for each region is shown on the bottom left of the Bland-Altman plots. The solid black line denotes the average mean of differences, while the dotted lines denote the limits of agreement (±1.96σ).

Discussion

This study shows that after an initial calibration based on auscultation, the Aktiia monitor is able to estimate SBP and DBP with accuracy for one month and in different body positions representative usual life in the elderly. To our knowledge, this is the first study reporting the performance of a cuffless optical device compared to double-blinded auscultation in an elderly cohort.

Overall acceptance rate was high and especially in sitting position (86%). As a comparison, a success rate of more than 70% of recordings is needed for satisfactory ambulatory blood pressure measurement (ABPM) interpretation [10]. The lowest acceptance was in standing position at 69%, however this rate was higher compared to the younger cohort at 45% in the same upright position [7]. The reason for this difference remains unclear since the signal quality could be modified by environmental factors such as outdoor and indoor temperature and patient-related factors, for example hydration status or respect of the protocol to remain calm and not moving during the recording. Note that the algorithm version used on each population was the same (version 6.0.2).

The performance of the Aktiia Monitor was best in terms of accuracy in the sitting position, thus meeting both criteria of modified ISO-81060-2 validation protocol developed for oscillometric devices but excluding cuffless, continuous and central monitors [11]. In all positions combined, the average difference was less

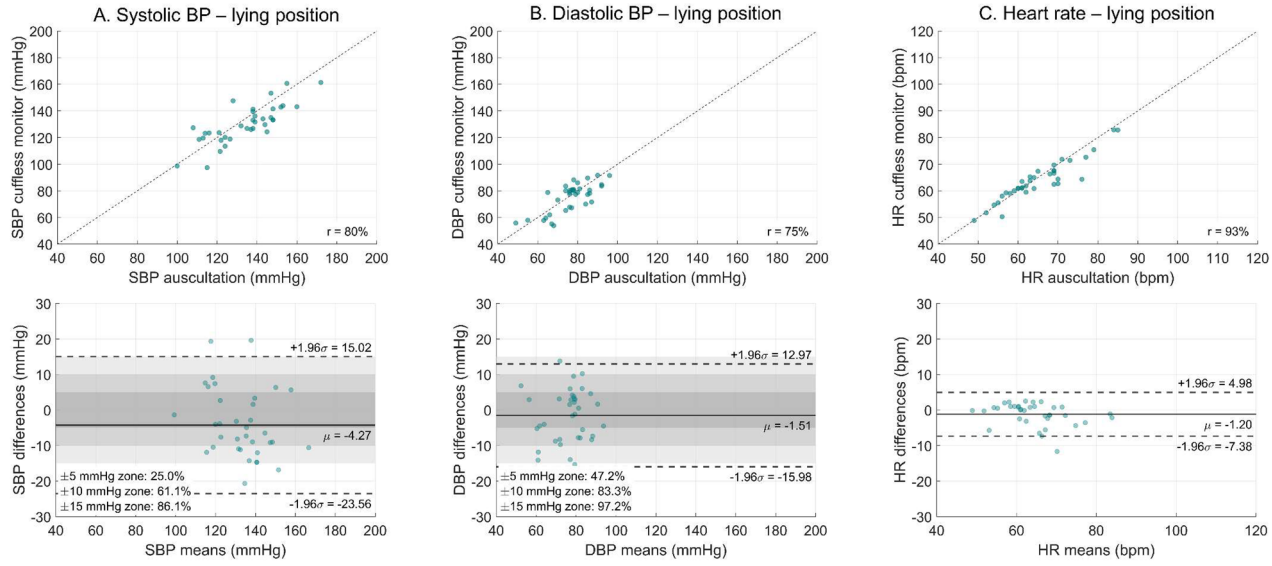


Figure 3. Scatter plots (upper) and Bland-Altman plots (bottom) comparing SBP (**A**), DBP (**B**) and HR (**C**) measurements performed by Aktiia monitor and double auscultation for lying position (BP) and pulse oximetry (HR).

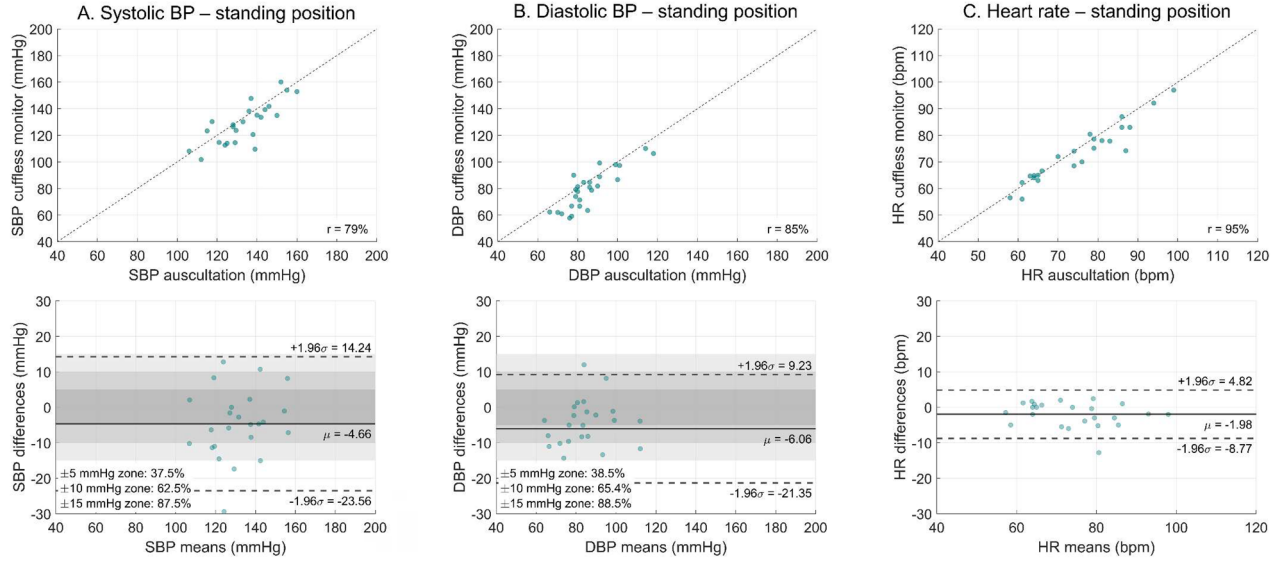


Figure 4. Scatter plots (upper) and Bland-Altman plots (bottom) comparing SBP (**A**), DBP (**B**) and HR (**C**) measurements performed by Aktiia monitor and double auscultation for standing position (BP) and pulse oximetry (HR).

than 1 mmHg compared to double auscultation for SBP and DBP. For the validation of cuffless devices, different pass requirements and validation protocols have been proposed some of which have been published after the completion of our study [8]. Each of the standards have their strengths and limitations in terms of practicality, feasibility and how stringent they are.

The average SBP and DBP was significantly higher in this elderly cohort compared to younger adults, which were evaluated with the same protocol [7]. This is consistent with the epidemiology of HTN which shows that prevalence of HTN increases with age and the phenotype of isolated systolic hypertension is predominant [12].

Interestingly, two recent studies have compared the Aktiia device to 24-hour ABPM [13, 14]. Both studies reported strong correlation of Aktiia's daytime BP with that of ABPM, but an overestimation of night-time BP with the Aktiia device. This may seem surprising since in our study the supine BP estimated with good accuracy compared to auscultation. However, the two cited studies compared an optical signal to the oscillometric technique which may be

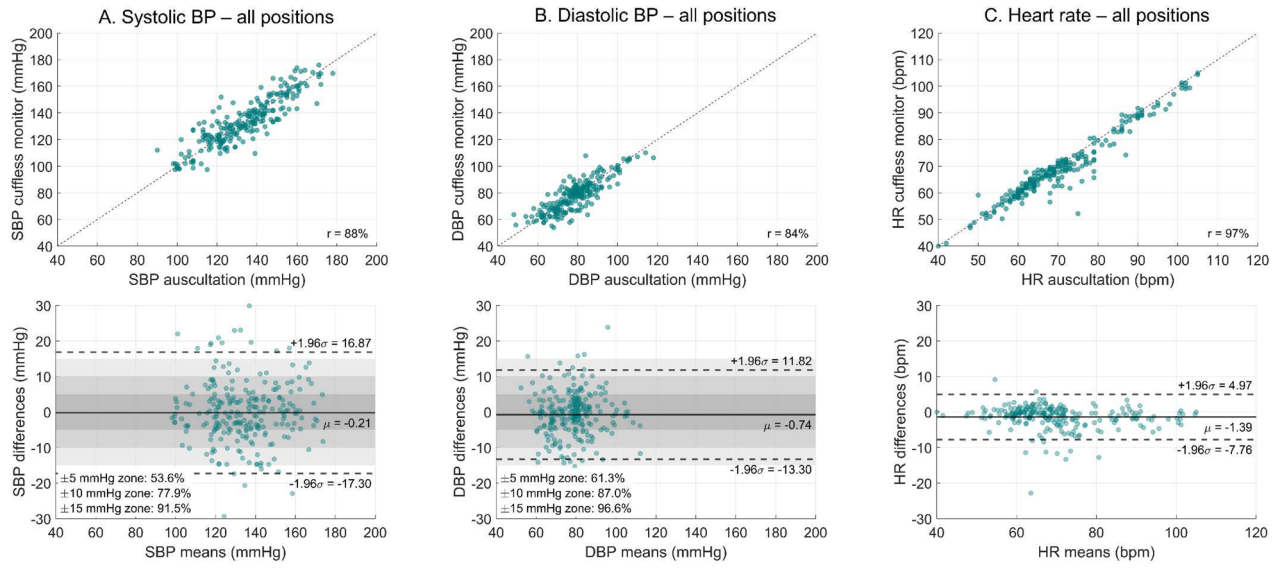


Figure 5. Scatter plots (upper) and Bland-Altman plots (bottom) comparing SBP (**A**), DBP (**B**) and HR (**C**) measurements performed by Aktiia monitor and double auscultation for all body positions (BP) and pulse oximetry (HR).

quite different from the auscultatory method and thus explain these finding partly [15]. The better reference method to be used to validate new device, outside invasive intra-arterial methods, remains to be determined [16].

Limitations

The absence of accepted standard for cuffless BP monitors at the time of study is one of the limitations of the study. The present study used the ISO 81060-2 protocol as a methodological reference to conduct the comparative exercises between Aktiia Bracelet and auscultation, while ensuring standardized sitting measurement conditions. Importantly, the validation protocols for cuff-based BP devices consider only sitting position, although ABPM device track BP for 24 hours and, naturally, in different body positions.

The Aktiia Bracelet is designed to measure BP only in the absence of motion of the wrist on which the device is placed, which includes positions such as sitting, standing, and lying. As such, measures might be different from ABPM which measures BP independently of motion and body position. In the context of accuracy, it is important to acknowledge, that these ABPM devices have not been validated in other positions than seated and relaxed. This is also true for the auscultation technique. Thus, a mean accuracy of less than 2 mmHg (except standing DBP) in each position seems within reasonable clinical limits.

Although the Aktiia Bracelet is designed to be monthly calibrated with a validated oscillometric device, in the present work initial calibration was performed in sitting position with the BP values measured during double auscultation. Calibration in sitting position might introduce position dependent calibration bias during pulse wave analysis [7], which might explain slightly lower accuracy in other position. As such, the Aktiia bracelet is not intended to replace ABPM or office BP at the present time but rather to facilitate measurement and bring new insights in daily pattern of BP.

According to ISO 81060-2, recruitment of study participants shall ensure that at least 5% of participants have a reference SBP less than or equal to 100 mmHg in each special cohort of the study. In this special cohort of older patients, the specific characteristic could not be fulfilled. The cohort had a restricted range of SBP and may not fully encapsulate the variations in arterial stiffness commonly observed in an elderly population [17]. Nevertheless, 43% of the study participants had SBP > 140 mmHg and, in some cases, treated with antihypertensive drugs, suggesting some level of representativeness. The primary focus of this work was to validate the cuffless BP monitor against a standard method under ISO81060-2 criteria, which we believe has been achieved.

Arterial stiffness and isolated systolic hypertension (Table 1), prevalent in elderly populations [12], warrant further investigation. Such pathophysiological conditions will be the subject of subsequent studies. The current findings, however, support the utility of the cuffless device in adhering to international

standards, thereby facilitating its potential role in hypertension management in diverse populations.

Perspectives

By 2050, the elderly population is expected to double across the world [19], which will inevitably increase the number of elderly hypertensives. Any initiative facilitating BP measurement for the diagnosis and the follow up will there be welcome. Cuffless BP technology is a promising solution as it is more comfortable than traditional cuff-based BP solutions. In addition, once calibrated and with stability of the optical signal over one month, the solution is appropriate and an elegant solution in this population with possible memory deficiency if adoption rate of connected devices and usability are high.

Conclusions

This study investigated the performance of the Aktiia optical BP monitor over one month after initial calibration compared to auscultation in an elderly population. The Aktiia Bracelet generated equivalent BP data compared to auscultation in sitting and relaxed position, as well as in other body positions. The use of more comfortable, non-invasive, and non-occlusive BP monitoring during long periods may facilitate e-health and may contribute to better management of HTN, including diagnosis and treatment of HTN, in the elderly.

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Authorship

Conception or design of the work: GW, JS and PV

Acquisition, analysis, or interpretation of data for the work: KT, JS, AD, TPA, AP, JA, PV and GW

Drafting the work or reviewing it critically for important intellectual content; KT, JS, AD, TPA, PV and GW

Final approval of the version to be published; all

Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved: JS, PV, TPA and GW

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ORCID

Josep Sola http://orcid.org/0000-0002-2005-5733
Aikaterini Damianaki http://orcid.org/0000-0003-2815-3650
Jérémy Alexandre http://orcid.org/0000-0001-7858-0285
Gregoire Wuerzner http://orcid.org/0000-0002-6424-7630

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Validation of the Aktiia blood pressure cuff for clinical use according to the ANSI/AAMI/ISO 81060-2:2013 protocol

Jérémy Alexandre[a], Kevin Tan[b], Tiago P. Almeida[a], Josep Sola[a], Bruce S. Alpert[c,*] and Jay Shah[a]

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Objective **Assess the accuracy and precision of the Aktiia initialization oscillometric upper-arm cuff device (Aktiia SA, Neuchâtel, Switzerland) for home blood pressure (BP) monitoring in the 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.**

Methods **Three trained observers validated BP measurements performed using the Aktiia cuff versus BP measurements performed using a standard mercury sphygmomanometer. Two ISO 81060-2 criteria were used to validate the Aktiia cuff. Criterion 1 evaluated, for both SBP and DBP, whether the mean error between BP readings performed by the Aktiia cuff and auscultation was ≤±5 mmHg, and whether the SD of the error was ≤8 mmHg. Criterion 2 assessed whether, for the SBP and DBP of each individual subject, the SD of the averaged paired determinations per subject of the Aktiia cuff and of the auscultation met the criteria listed in the table of Averaged Subject Data Acceptance.**

Results **Mean differences between the Aktiia cuff and the standard mercury sphygmomanometer (criterion 1) were 1.3 ± 7.11 mmHg for SBP and −0.2 ± 5.46 mmHg for DBP. The SD of the averaged paired differences per subject (criterion 2) was 6.55 mmHg for SBP and 5.15 mmHg for DBP.**

Conclusion **Aktiia initialization cuff complies with the requirements of the ANSI/AAMI/ISO guidelines and can be safely recommended for BP measurements in the adult population.** ***Blood Press Monit*** **28: 109–112 Copyright © 2023 The Author(s). Published by Wolters Kluwer Health, Inc.**

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Keywords: blood pressure, calibration, clinical investigation, cuffless blood pressure monitor, initialization, optical signals, validation

[a]Aktiia SA, Neuchâtel, Switzerland, [b]Guangdong Transtek Medical Electronics, Zhongshan, China and [c]Retired from Department of Pediatrics, University of Tennessee Health Science Center, Memphis, Tennessee, USA

Correspondence to Jay Shah, MD, Aktiia SA, Rue du Bassin 8a, Neuchâtel 2000, Switzerland
Tel: +41 32 552 20 52; fax: +41 31 4159 2653; e-mail: publication@aktiia.com

*Bruce S. Alpert retired.

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Introduction

Hypertension is a major cause of preventable death in the world [1–3]. Blood pressure (BP) measurement is recommended for diagnostics and long-term hypertension management [1–3]. Accordingly, the validation of BP measurement devices is critical to support accurate hypertension diagnostic and medication titration [4,5]. Currently, many BP devices are commercialized prior to validation, which hinders adequate hypertension management and consumers' access to validated BP devices [6,7].

Aktiia SA (Neuchâtel, Switzerland) has developed a Conformité Européenne-marked, non-invasive, cuffless BP monitor (Fig. 1). The Aktiia monitor requires a once-a-month initialization procedure that recalibrates measurements using BP readings performed by the Aktiia cuff (Fig. 1a). Although the Aktiia monitor has been thoroughly investigated in previous studies [8–13] and the Aktiia cuff has been fully validated according to the International Organization for Standardization (ISO) 81060-2 protocol, the publication of the results for the Aktiia cuff validation is still pending [5].

In the present work, we sought to validate the Aktiia cuff for upper-arm BP measurements in accordance with the American National Standards Institute / Association for the Advancement of Medical Instrumentation / International Organization for Standardization (ANSI/AAMI/ISO) 81060-2:2013 protocol [5].

Methods

The Aktiia cuff

The Aktiia cuff is manufactured by Guangdong Transtek Medical Electronics Co., Ltd (Zhongshan, China). Transtek was responsible for data collection and protocol implementation during the study. The Aktiia cuff is designed for BP measurements at the upper arm. It is provided with a USB cable to recharge its internal

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Fig. 1



Illustration of the Aktiia monitor with (a) the Aktiia cuff, (b) the Aktiia bracelet and (c) the associated smartphone application to visualize SBP and DBP.

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battery and is equipped with Bluetooth technology that supports communication with the Aktiia smartphone application. The Aktiia cuff performs BP measurements in the range of 0–299 mmHg, and heart rate (HR) within 40–199 bpm. It is a one-size-fits-all cuff, which can be adjusted around the user's arm (arm circumference between 22 and 42 cm).

Study population

The Aktiia cuff was tested on 99 subjects following the ANSI/AAMI/ISO protocol, 2013. All subjects were volunteers recruited at Zhongshan's City People Hospital (Zhongshan, China). Subjects with any two reference SBP values that differ by more than 12 mmHg or any two reference DBP values that differ by more than 8 mmHg were excluded from the study (14 subjects excluded). The demographic and clinical characteristics of the study population included in this study (85 subjects) are shown in Table 1.

Table 1 Demographic and clinical characteristics of the study population (*N*=85)

Age, years	43.2±17.2 [18–77]
Prevalence of	
The elderly (>60 years)	36%
Obesity (BMI≥30 kg/m^2)	48%
Male/female	38/47 [45%/55%]
Arm circumference, cm	32.8±5.4 [22–42]
Arm circumference, cuff specified range	
Lower half	41.2%
Upper half	58.8%
Lower quarter	22.4%
Upper quarter	22.4%
Lower octal	5.9%
Upper octal	9.4%
SBP, mmHg	126.6±16.0 [84–162]
≤100	5.9%
≥140	20.0%
≥160	5.5%
DBP, mmHg	79.2±12.3 [53–120]
≤60	6.7%
≥85	29.0%
≥100	5.1%

Numbers represented as $(\mu \pm \sigma)$ [range].

This study was approved by the Zhongshan People's Hospital Ethics Committee with written informed consent obtained from each subject.

Study protocol

Study subjects were seated in a quiet room at a comfortable temperature and instructed not to move or speak during the procedure. Subjects were requested to place their feet flat on the floor. The arm circumference of each subject was measured before the start of the procedure. BP measurements started at least 5 min after the participants were seated. All BP measurements were performed on the participants' left arm at the heart level. Accordingly, the Aktiia cuff was placed on the subjects' left arm at heart level, and the double stethoscope was placed on the inner part of the elbow joint for recording Korotkoff sounds.

Blood pressure measurements validation

BP measurements were conducted by three observers experienced in BP measurement. BP measurements were conducted following the same-limb sequential procedure described in the ISO 81060-2:2013 protocol [5], with alternating measurements performed with the Aktiia cuff and a mercury sphygmomanometer. Simultaneous auscultatory measurements were performed by two observers blinded from each other using a double stethoscope (T piece) via the Korotkoff method. The third observer recorded the device readings and supervised the BP readings made by the first two observers.

Data analysis

Data analyses were performed as delineated in the ANSI/AAMI/ISO protocol. Auscultation BP measurements were computed as the average between the readings performed by the two observers before and after each device reading. The Aktiia cuff performed automated BP readings by oscillometry. The two criteria for ISO 81060-2 validation were investigated [5].

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Statistical analysis

The results of the comparisons are expressed as mean ± SD ($\mu \pm \sigma$).

Bland–Altman plots were created to highlight individual-level measurements. Additionally, regions of interest (ROIs) within ±5 mmHg, ±10 mmHg and ±15 mmHg were included to assess levels of agreement [14].

Additionally, results extending the ISO 81060-2 requirements are shown in the Supplementary materials, Supplemental digital content 1, *http://links.lww.com/BPMJ/A186*.

Results

Table 2 and Fig. 2 summarize the results for criteria 1 and 2 of ISO 81060-2. For criterion 1, the bias and SD ($\mu \pm \sigma$) found between Aktiia cuff and reference double-auscultation for SBP were 1.3 ± 7.11. For DBP, the bias and SD were −0.2 ± 5.46. For criterion 2, the SD of the averaged paired differences per subject was 6.55 mmHg for SBP and 5.15 mmHg for DBP – also within the limits delineated by ISO 81060-2.

Additionally, the two modalities resulted in SBP agreements of 53%, 86% and 96% within the ±5 mmHg, ±10 mmHg and the ±15 mmHg ROIs, respectively (Fig. 2). Similarly, the two modalities resulted in DBP agreements of 69%, 95% and 99% within the ±5/±10/±15 mmHg ROIs, respectively.

Discussion

In the present study, we investigate the accuracy of the Aktiia initialization oscillometric upper-arm cuff device for home BP monitoring in the general population according to the ANSI/AAMI/ISO 81060-2:2013 standard.

Our study demonstrates that the accuracy of SBP and DBP values measured by the Aktiia cuff satisfying the criteria defined by ISO 81060-2:2013 [5]. The tested oscillometric device fulfils the same requirements as any validated upper-arm device available on the market. Consequently, the Aktiia cuff is validated according to international standards and is thus recommended for use in clinical practice.

Cuffless blood pressure monitors

The Aktiia cuff will be integrated into the Aktiia System and will be used to initialize Aktiia's cuffless BP monitor, allowing users to perform on-demand readings. The Aktiia cuffless monitor comprises a small bracelet (Fig. 1b) that contains optical sensors to collect photoplethysmography signals acquired on the user's wrist. Pulse wave analysis is applied to the photoplethysmography signals to estimate SBP, DBP and HR, which are displayed in a smartphone application (Fig. 1c). This over-the-counter fully automated device is ideal for long-term continual BP monitoring in daily conditions.

Cuffless BP devices offer a new perspective and strategy for continual BP monitoring. The validation of the Aktiia cuff in the sitting position is a first step towards this paradigm change in the management of hypertension.

Limitations

The present validation was performed in early 2019 following the recommendations of the ISO 81060-2:2013 standard that was applicable then, and its data supported the immediate commercialization of the Aktiia System across Europe. In November of the same year, a new version of the ISO 81060-2 was released (EN ISO 81060-2:2019). The Aktiia cuff also complies with the procedures described by this new version of the standard, except for the lower and upper octal arm circumferences found in the present cohort (Table 1). The presented results, however, support that the Aktiia Initialization cuff can be safely recommended for BP measurements in the adult population.

The Aktiia cuff is produced and tested by Guangdong Transtek Medical Electronics, which might lead to potential conflicts of interest. We believe, however, that the results shown in the present work are representative since Transtek implemented all methods in accordance with the guidelines described in the ISO 81060-2 standard. Additionally, all data collected during the validation study have been recorded and stored and can be accessed upon request for further verification.

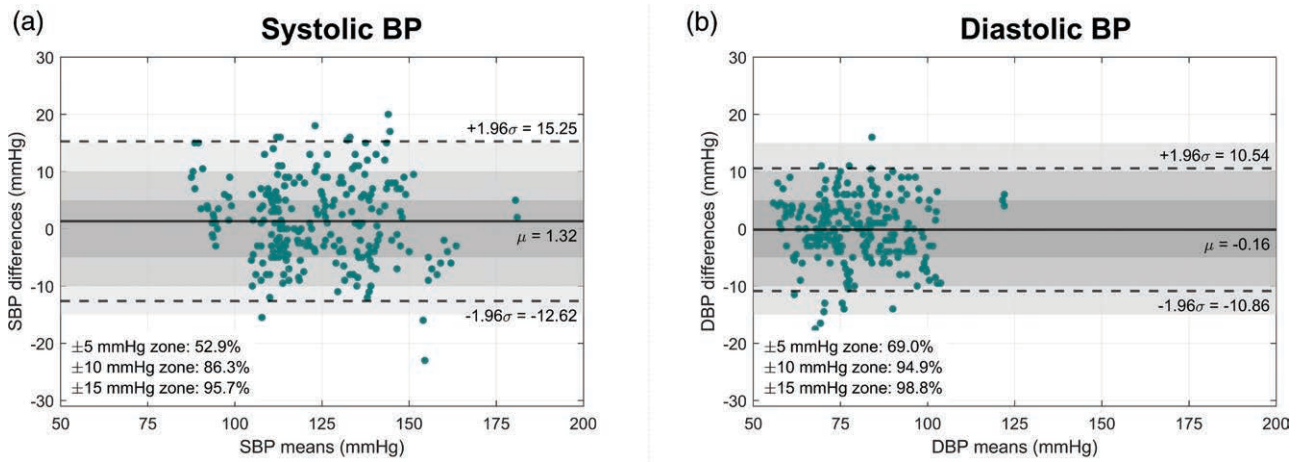
Conclusion

In the present work, we validated the Aktiia cuff for upper-arm BP measurements following the ANSI/AAMI/ISO 81060-2:2013 protocol. Our results show that the Aktiia cuff complies with the requirements of the ANSI/AAMI/ISO guidelines and can be safely recommended for BP measurements in the adult population. This is of paramount importance for an accurate once-a-month initialization procedure that recalibrates measurements using the Aktiia cuffless monitor. Therefore, the Aktiia monitor can be effectively used for non-invasive, self-triggered,

Table 2 Mean and SD of the differences between Aktiia cuff and reference

	Criterion 1				Criterion 2		
	Mean error	ISO target	SD	ISO target	SD of averaged differences per subject	ISO target	Result
SBP (mmHg)	1.3	≤±5.0	7.11	≤8.00	6.55	≤6.82	Pass
DBP (mmHg)	−0.2	≤±5.0	5.46	≤8.00	5.15	≤6.95	Pass

Fig. 2



Bland–Altman plots comparing (a) SBP and (b) DBP measurements performed by the Aktiia cuff and the reference double-auscultation. ROIs within ±5 mmHg, ±10 mmHg and ±15 mmHg are highlighted in dark grey and light grey, respectively. The percentage of agreement for each region is shown on the bottom left of the Bland–Altman plots. The solid black line denotes the average mean of differences, while the dotted lines denote the limits of agreement (±1.96σ). ROIs, regions of interest.

intermittent SBP and DBP monitoring in adult patients when the user is sitting and the device is calibrated.

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Conflicts of interest

The Aktiia cuff is produced (and tested) by Guangdong Transtek Medical Electronics. B.S.A. serves as a consultant for Aktiia SA. For the remaining authors, there are no conflicts of interest.

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KNOWLEDGE, PERCEPTION, AND PRACTICE OF QUEBEC HEALTH PROFESSIONALS REGARDING AMBULATORY AND CLINIC BLOOD PRESSURE MEASUREMENT METHODS

Shweta Todkar[1], *Raj Padwal*[2], *Lyne Cloutier*[3]. [1]Quebec Heart and Lung Institute-University Laval, Department of Pharmacy, Quebec, CANADA, [2]University of Alberta, Department of Medicine, Alberta, CANADA, [3]University of Quebec at Trois-Rivieres, Department of Nursing, Quebec, CANADA

Objective: Hypertension Canada Guidelines recommend using standardized methods of blood pressure measurement (BPM), namely home (HBPM), ambulatory (ABPM), office (OBPM), and automated (AOBP) for hypertension management. Health professionals (HP), namely nurses, physicians, and pharmacists, routinely perform BPM, but their knowledge, perception, and practice concerning all methods is understudied, including in Canada, and results show critical gaps with the guidelines. This descriptive study is the first to establish a portrait primary care HP's in Quebec concerning the four BPM methods.

Table 1. Mean knowledge and perception scores of HPs for all BPM methods

Concepts	Score% M±SD		
	Nurses (n=453)	Physicians (n=45)	Pharmacists (n=30)
Knowledge	46% ± 23	52% ± 16	60% ± 16
Perception	73% ± 8	71% ± 7	72% ± 5

Design and method: All licensed primary care HP's in Quebec were targeted. A validated and pretested investigator-initiated BPM questionnaire in English and French was used for data collection. In December 2019, physicians and pharmacists were recruited through their associations' monthly newsletter, while nurses received a personalized email invitation with a link to a secured platform. UQTR issued the certificate of ethics.

Results: A total of 453 nurses, 45 physicians, and 30 pharmacists participated in the study. The median age was 40 ± 11 years for nurses, 50 ± 13 years for physicians, and 42 ± 12 for pharmacists. The overall knowledge and perception scores for BPM methods are presented in Table 1. In practice, physicians frequently use HBPM for diagnostic purposes (73%), treatment (91%), and follow-up (86%), while HBPM was recommended by 47% of nurses and 53% of pharmacists. Overall, ABPM was used less frequently (<50% of the time) by all HP's. In the clinic, the auscultatory method is still used by a significant percentage of nurses (11%), physicians (32%) and pharmacists (7%), while only 25% nurses, 13% physicians and 30% pharmacists use the AOBP method.

Conclusions: Overall, knowledge was suboptimal for nurses and somewhat optimal for physicians and pharmacists. Practice was unsatisfactory for all HPs. Training and continuing education should be encouraged and should be renewed with the newest education methods along with practice assessment.

ACCURACY OF THE AUTOMATED OSCILLOMETRIC HOME BLOOD PRESSURE MONITOR BRAUN BUA4000 WITH WIDE RANGE CUFF: VALIDATION ACCORDING TO THE AAMI/ESH/ISO UNIVERSAL STANDARD

Ariadni Menti, Angeliki Ntineri, Vasileios Ntousopoulos, Aikaterini Theodosiadi, Panagiota Stathopoulou, Konstantinos Kyriakoulis, Anastasios Kollias, George S. Stergiou. Hypertension Center STRIDE-7, University of Athens, Third Department of Medicine, Sotiria Hospital, Athens, GREECE

Objective: To evaluate the blood pressure (BP) measurement accuracy of the Braun BUA4000 automated oscillometric upper-arm cuff device for self-home use in a general population according to the Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO) Universal Standard (ISO 81060-2:2018) and its Amendment 1.2020-01.

Design and method: Participants were recruited to fulfil the age, sex, BP, and limb distribution criteria of the AAMI/ESH/ISO Universal Standard in general population using the same arm sequential BP measurement method. A single wide-range cuff of the test device was used for arm circumference range 22-42 cm.

Results: A total of 98 individuals were recruited and 85 were analyzed (mean age 60.3±16.1 [SD] years, 44 men, arm circumference 31.5±5.1 cm, range 22-41.5 cm). For validation Criterion 1, the mean difference ±SD between the test device and reference BP readings (N = 255) was 0.9±6.4/-0.3±6.4 mmHg (systolic/diastolic; threshold < = 5±8 mmHg). For Criterion 2, the SD of the averaged BP differences between the test device and reference BP per individual (N = 85) was 5.15/5.81 mmHg (systolic/diastolic; threshold < = 6.88/6.95 mmHg).

Conclusions: The Braun BUA4000 automated oscillometric home BP monitor fulfilled all the requirements of the AAMI/ESH/ISO Universal Standard (ISO 81060-2:2018) in a general population and can be recommended for clinical use.

AN EQUIVALENT MEASUREMENT PERFORMANCE OF THE AKTIIA BRACELET IS OBSERVED IN THE ADULT AND ELDERLY POPULATIONS

Tiago Paggi de Almeida[1], *Aikaterini Damianaki*[2], *Josep Sola*[1], *Kenji Theiler*[2], *Jérémy Alexandre*[1], *Pascale Vermare*[1], *David Perruchoud*[1], *Jay Shah*[1], *Grégoire Wuerzner*[2]. [1]Aktiia SA, Neuchâtel, SWITZERLAND, [2]Lausanne University Hospital, CHUV, Lausanne, SWITZERLAND

Objective: It remains unclear whether non-occlusive blood pressure (BP) monitoring devices yield equivalent performance across different age categories. We sought to compare the performance of BP measurements conducted by the Aktiia cuffless monitor in the adult and elderly populations, in different body positions.

Design and method: Two cohorts of patients (adult, 21-65 years; elderly, 65-85 years) were recruited for a prospective clinical study (NCT04027777, Lausanne University Hospital, Switzerland, August/2019–March/2022). During 4 visits spread over a month, systolic/diastolic BP (SBP, DBP) measurements obtained by the cuffless Aktiia G1 Bracelet (Aktiia SA, Switzerland) were compared to double-blinded auscultation in sitting, standing and lying positions after initial calibration. The two ISO 81060-2 criteria were used to compare BP measurements by Aktiia and auscultation (BP-reading-level – criterion 1; subject-level – criterion 2) in the sitting position – as no ISO criteria exists so far for other body positions.

Results: 96 adult (38±12 years)/35 elderly (73±6 years) were included in the study. Of those, 84 adult/35 elderly patients were investigated in sitting position; 91 adult/35 elderly in all body positions. Average SBP and DBP were higher in the elderly cohort (SBP 133.9±17.7 vs. 116.4±20.3 mmHg, P<0.0001; DBP 77.9±11.7 vs. 74.5±12.0 mmHg, P<0.0001). On sitting position at BP-reading-level, SBP and DBP for both cohorts were within ISO targets for mean error and SD (Table 1). At subject-level, the SD of the mean paired differences per subject were within individual ISO targets for SBP and DBP on both cohorts. Statistically significant differences between cohorts were found only at BP-reading-level for all body positions (SBP: P = 0.0127; DBP: P = 0.0199). Figure 1 highlights the biases and correlations of SBP and DBP readings between the cuffless BP monitor and auscultation for both adult and elderly cohorts.

Table 1. Comparisons of accuracy (BP-reading-level) and precision (subject-level) between Adult and elderly cohorts for SBP and DBP measurements performed by the cuffless BP monitor and reference double-auscultation. Unpaired t-test was conducted to compare the mean differences between cohorts at BP-reading-level and subject-level. N.A., non-applicable. ***Significantly different.**

			Analysis at BP-reading-level						Analysis at subject-level			
			Statistics for each cohort (ISO 81060-2 Criterion 1)				Cohort comparison (t-test)		Statistics for each cohort (ISO 81060-2 Criterion 2)		Cohort comparison (t-test)	
Body position	Blood pressure	Cohort	Mean error	ISO Target	SD	ISO Target	Test statistics	P-value	SD of mean of differences	ISO Target	Test statistics	P-value
Sitting	SBP (mmHg)	Adult	0.16	≤±5	7.92	≤8	-1.43 ± 7.91	0.1520	4.15	≤6.95	-0.56 ± 4.05	0.5744
		Elderly	1.23		7.88				3.78	≤6.84		
	DBP (mmHg)	Adult	0.79		6.25		1.04 ± 6.00	0.2967	3.27	≤6.89	1.21 ± 3.06	0.2278
		Elderly	0.20		5.55				2.48	≤6.95		
All	SBP (mmHg)	Adult	-1.86	N.A.	9.98	N.A.	**-2.50 ± 9.98**	**0.0127***	5.28	N.A.	-1.04 ± 5.06	0.3003
		Elderly	-0.26		9.96				4.42			
	DBP (mmHg)	Adult	0.29		6.95		**2.33 ± 6.96**	**0.0199***	3.76		1.53 ± 3.75	0.1289
		Elderly	-0.75		6.98				3.71			

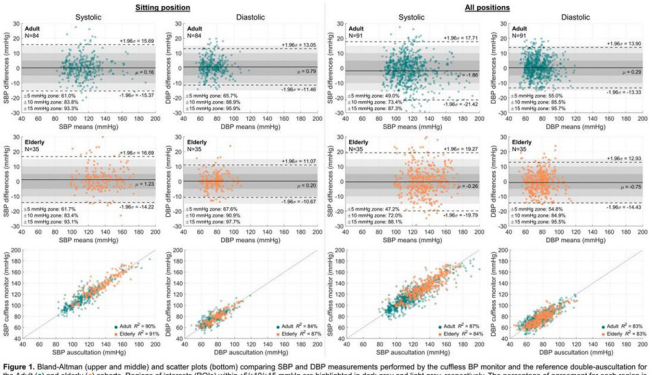


Figure 1. Bland-Altman (upper and middle) and scatter plots (bottom) comparing SBP and DBP measurements performed by the cuffless BP monitor and the reference double-auscultation for the Adult (●) and elderly (●) cohorts. Regions of interests (ROIs) within ±5/±10/±15 mmHg are highlighted in dark grey and light grey, respectively. The percentage of agreement for each region is shown on the bottom left of the Bland–Altman plots. The solid black line denotes the average mean of differences, while the dotted lines denote the limits of agreement (±1.96σ). Pearson's correlation (R^2) between the two modalities for both cohorts are shown on the bottom right of the scatter plots.

Conclusions: The investigated cuffless BP monitor yielded equivalent BP measurements compared to auscultation, with similar performance in the adult and elderly populations.

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Validation of the optical Aktiia bracelet in different body positions for the persistent monitoring of blood pressure

Josep Sola[1]✉, Anna Vybornova[1], Sibylle Fallet[1], Erietta Polychronopoulou[2], Arlene Wurzner-Ghajarzadeh[2] & Gregoire Wuerzner[2]

The diagnosis of hypertension and the adjustment of antihypertensive drugs are evolving from isolated measurements performed at the physician offices to the full phenotyping of patients in real-life conditions. Indeed, the strongest predictor of cardiovascular risk comes from night measurements. The aim of this study was to demonstrate that a wearable device (the Aktiia Bracelet) can accurately estimate BP in the most common body positions of daily life and thus become a candidate solution for the BP phenotyping of patients. We recruited 91 patients with BP ranging from low to hypertensive levels and compared BP values from the Aktiia Bracelet against auscultatory reference values for 4 weeks according to an extended ISO 81060-2 protocol. After initializing on day one, the observed means and standard deviations of differences for systolic BP were of 0.46 ± 7.75 mmHg in the sitting position, − 2.44 ± 10.15 mmHg in the lying, − 3.02 ± 6.10 mmHg in the sitting with the device on the lap, and − 0.62 ± 12.51 mmHg in the standing position. Differences for diastolic BP readings were respectively of 0.39 ± 6.86 mmHg, − 1.93 ± 7.65 mmHg, − 4.22 ± 6.56 mmHg and − 4.85 ± 9.11 mmHg. This study demonstrates that a wearable device can accurately estimate BP in the most common body positions compared to auscultation, although precision varies across positions. While wearable persistent BP monitors have the potential to facilitate the identification of individual BP phenotypes at scale, their prognostic value for cardiovascular events and its association with target organ damage will need cross-sectional and longitudinal studies. Deploying this technology at a community level may be also useful to drive public health interventions against the epidemy of hypertension.

Blood pressure (BP) is a strong predictor of cardiovascular risk when it is measured accurately and in a standardized way[1]. However, epidemiologic data show that prediction of risk is largely improved when BP is measured out of the doctor's office. Accordingly, the latest international guidelines recommend more widespread use of out-of-office BP measurements for the diagnosis and follow-up of hypertension[1–3].

Today, out-of-office measurements of BP are mostly performed by a series of self-measurements done at home and for long periods: the so-called Home Blood Pressure Monitoring (HBPM) method. Alternatively, patients may wear a device that repeatedly measures BP for 24 h: the so-called Ambulatory Blood Pressure Monitoring (ABPM) method[4].

With both monitoring methods, different patterns of abnormal BP variability have been described in the last decades: namely white-coat hypertension, masked hypertension, nocturnal non-dipping, nocturnal extreme-dipping, nocturnal rising, nocturnal hypertension or high BP variability[5]. A growing body of evidence shows that such abnormal BP phenotypes are associated with an increase in cardiovascular events when compared to normal circadian rhythms, independently of BP readings from the physician office[6]. Based on this data, the universal large-scale cardiovascular risk assessment based on BP phenotyping should be the next step in the fight against hypertension and its associated cardiovascular disease. However, the current HBPM/ABPM available devices still rely on a technology that restricts out-of-office BP measurements, can be uncomfortable and sparse and is finally relatively expensive and only accessible to a limited fraction of the population[7]. Several authors have described clinical utilities of these office and out-of-office BP measurement methods and are combined and scored in Table 1[8–13].

[1]Aktiia SA, Rue du Bassin 8a, 2000 Neuchâtel, Switzerland. [2]Service of Nephrology and Hypertension, CHUV - Lausanne University Hospital and University of Lausanne, Lausanne, Switzerland. ✉email: josep@aktiia.com

	Clinical use	Office BP	Home BP	Ambulatory BP	Pharmacy BP	Wearable Persistent BP
Individual scale	Screening	+++[a]	+[a]	-[a]	++[a]	✓
	Initial diagnosis	+[a]	++[a]	+++[a]	-[a]	✓
	Initial phenotyping			++[b]		✓
	Treatment titration based on thresholds	+[a]	++[a]	++[a]	-[a]	✓
	Treatment titration based on individual dynamic phenotyping			++[c]		✓
	Follow-up	++[a]	+++[a]	+[a]	+[a]	✓
Population scale	Screening of communities	++[d]	+++[e]		+++[f]	✓
	Phenotyping of communities					✓
	Titration of public health interventions				+++[f]	✓

Table 1. Scores on the potential use and utility of office BP, home BP, ambulatory BP and pharmacy BP taken from[8] (marked by[a]), [9] (marked by[b]), [10] (marked by[c]), [11] (marked by[d]), [12] (marked by[e]) and [13] (marked by[f]).

In the digital era, wearable devices have already started to measure basic cardiovascular parameters. Empowered by optical sensors embedded on smartwatches and smart bands, a large catalogue of cardiovascular indicators can now be measured continuously, non-invasively and unnoticed by the wearer. The basic parameters that can be monitored by these devices range from heart rate, heart rate variability, detection of atrial fibrillation, SpO_2, actigraphy to sleep patterns[14]. However, reliable, and validated devices measuring BP in different body positions and repeatedly over 24 h are unavailable so far.

The potential impact of widespread monitoring of BP through the optical sensors embedded on wearable devices is extensive: a 24/7 BP device would be an excellent candidate to not only provide an alternative to HBPM/ABPM in terms of cost-efficiency and patient adherence but also to extend existing use-cases by providing insights into individual daily, monthly and yearly BP rhythms. This would enable the first-ever large-scale phenotyping of populations in addition to driving personalized approaches for the diagnosis and the management of hypertension[15,16]. Table 1 marks with ✓ the uses and utilities that wearable persistent BP monitors have the potential to support.

The Aktiia Bracelet is a wearable CE-marked Class lla medical device (Fig. 1) that records optical signals at the wrist and transforms them into the BP values using pulse wave analysis algorithms after an initial calibration procedure based on a series of oscillometric measurement performed by an upper arm cuff[17]. The device and technology have already been validated according to international standards against invasive arterial line measurements in the lying position in ICU settings[18], and against auscultation measurements in the sitting position[19]. However, the potential of this device goes beyond on-demand measurements when a patient is sitting or lying. Indeed, the Aktiia Bracelet allows automatic BP measurements in any body and arm positions as long as the arm is still, removing thus the need of the user to initiate a measurement and enabling thus persistent day and night BP monitoring.

In this paper, we report the performance of the optical Aktiia Bracelet to that of manual double-blinded auscultation measurements in a representative cohort of participants measured in different body positions. As such, we provide the first evidence of the feasibility of persistent BP monitoring via optical sensors at the wrist. Following these results, we propose a possible framework for the large-scale deployment of BP phenotyping of populations based on wrist-worn wearable devices that integrate optical sensors, and we outline the possible implications that these devices might have on global awareness and control of high BP.

Methods

Ethical consent and study registration. The study[20] was approved by the local Ethics Committee (CER-VD—Commission cantonale d'éthique de la recherche sur l'être humain, CH 1012 Lausanne, Switzerland, authorization no. 2019-01046 of 06/08/2019) and the Swiss authority responsible for the authorization and supervision of therapeutic products (Swissmedic, CH-3012 Bern, Switzerland, authorization no. 10000542 of 29/07/2019). The study was registered in EUDAMED (registration no. CIV-19-06-029004 of 29/07/2019) and ClinicalTrials.gov (registration no. NCT04027777 of 22/07/2019).

All study participants signed an informed consent form prior to study procedures. The study was conducted according to the current version of the World Medical Association Declaration of Helsinki, ICH-GCP guidelines and ISO 14155. No adverse event was reported during this clinical investigation.

Study objectives and outcomes. The main objective of the study was to demonstrate the accuracy and precision of BP values estimated by the Aktiia Bracelet when compared to BP readings obtained by manual dou-



Figure 1. The Aktiia 24/7 BP monitor is a wearable device that persistently measures optical signals on the skin vasculature of the wrist and displays day and night BP values on a companion smartphone application. The Aktiia Bracelet is a CE-marked class IIa medical device.

ble-auscultatory in the most common body positions of daily life. The study outcomes were the mean and the standard deviation of the differences of the readings of the two measurement modalities in each body position.

Study population. The study population included a representative cohort of male and female patients (N = 91) aged between 21 and 65 years old (38 ± 13 years), with body mass index (BMI) between 18 and 41 kg/m^2 (24.0 ± 4.7 kg/m^2) and presenting different skin pigmentations and different hair follicle densities. The cohort covered all BP categories ranging from hypotensive to hypertensive as required by ISO 81060-2:2013 except for the requirement that 20% of readings shall have SBP ≥ 140 mmHg: this deviation resulted from a multi-factorial recruitment process that included, on top of the inclusion criteria of ISO 81060-2:2013, additional constraints on skin pigmentation, wrist hair follicle density, and age distribution. Yet, the recruited cohort represented all relevant BP phenotypes, including 24% of the patients presenting either SBP ≥ 140 mmHg or DBP ≥ 100 mmHg (hypertensive phenotype), and 24% of the patients presenting either SBP ≤ 100 mmHg or DBP ≤ 60 mmHg (hypotensive phenotype). Note that 91 patients were recruited instead of 85 (as required by ISO81060-22,013) in order to fulfil the described multi-factorial recruitment process. Patients with a wrist circumference larger than 22 cm were exclude from the study because the Aktiia Bracelet would not fit their wrist. Full details on the study recruitment matrix are available in a previous publication[19].

Experimental set-up. The study was held at the Lausanne University Hospital (Switzerland) and consisted of 4 visits over 1 month, i.e. at days 1, 9 ± 3, 18 ± 3, and 29 ± 3, involving a series of assessments in different body positions (sitting with de device at the heart level, sitting with the device on the lap, lying and standing) at each visit (Fig. 2). Each study participant was equipped with a manual sphygmomanometer on the left upper arm, and an Aktiia Bracelet on the right wrist. Each assessment of the study consisted of the simultaneous recording of optical signals with the Aktiia Bracelet and the reading of reference BP values by double-auscultation. As

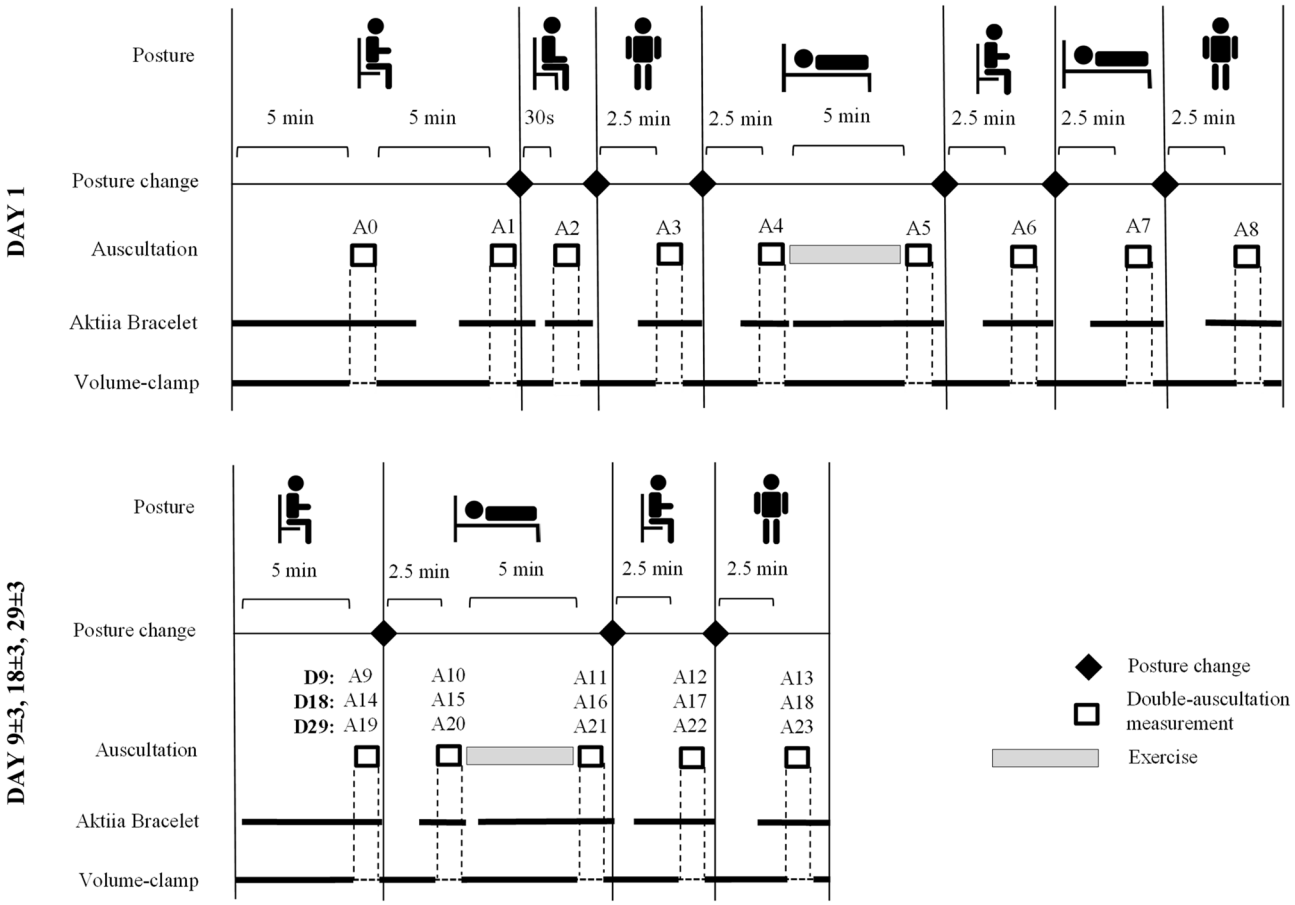


Figure 2. Schematic representation of the protocol designed to evaluate the performance of a cuffless BP monitor intended to be used in 24/7 environments. At each visit, assessments involving the reference device and the device under test are performed in varying body positions such as sitting, lying and standing positions, and after exercise. Visits are further repeated in order to test the stability of the device.

described and explained previously[19], this was based on the requirements of the opposite limb simultaneous method described in ISO 81060-2:2013, excluding the use of alternating arms. The recording of an optical signal consisted of the acquisition of 30 s of green reflective photo-plethysmography[21] at 100 samples per second. The reading of a reference BP value consisted of the identification of the K1 and K5 Korotkoff sounds by two experienced observers during the manual deflation of the sphygmomanometer cuff. Full disclosure of the implemented measuring methods is provided in[19].

Participants were also equipped with a volume-clamp device on the left arm to be used as a reference-control device for changes in BP induced by different body positions (Nexfin BMYE, Netherlands). For this purpose, a finger cuff of appropriate size was positioned on the participant's left middle finger and continuously monitored finger arterial pressure throughout the entire duration of the visit (Fig. 3).

Measurement procedures in addition to sitting and relaxed conditions. To assess the performances of the Aktiia Bracelet on the realistic ambulatory scenario of BP monitoring around the clock, the protocol included BP assessments in different body postures: sitting and relaxed, lying supine and standing (Fig. 2). A 5-min aerobic exercise was also performed at each visit to assess the ability of the Aktiia Bracelet to capture large BP changes. In addition, and to assess the effect of the arm position related to the heart level in the performance of the device, measurements with the arm on the lap (i.e. below the heart level) were also performed. Each BP assessment in each described condition consisted of a simultaneous recording of optical signals with the Aktiia Bracelet, a BP measurement using double-auscultation, and a BP measurement using volume-clamp.

Limits of the auscultatory technique as a reference method. When used in patients that are "seated and relaxed", double auscultation is widely used as a reference method for the validation of BP monitors. However, the goal of the present study was to assess the performances of a wearable device when used in 24/7 conditions, including positions other than sitting (lying and standing) and after physical activity (aerobic exercise). Our group has recently published experimental data[22] suggesting that the reliability of auscultation in other conditions than such "seated and relaxed" can be compromised if the vascular tonus of the brachial artery is altered. To mitigate the uncertainty introduced by double auscultation in such non-standard measurement conditions,

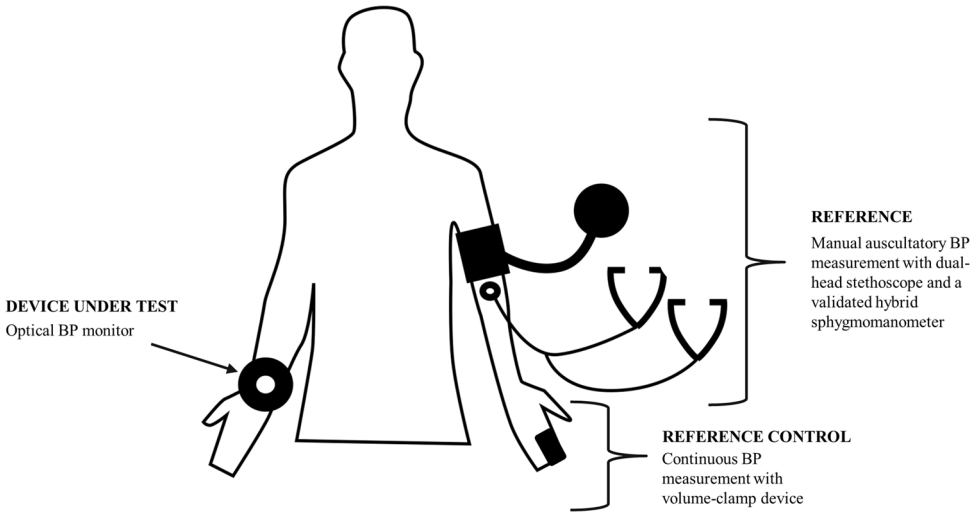


Figure 3. Experimental set up of the required equipment to investigate the performance of a BP monitor intended to be used in 24/7 environments. Reference BP values are obtained by a validated hybrid sphygmomanometer and auscultation with a dual-head stethoscope. Changes in auscultation values with different body positions are controlled by the continuous measurements of an ipso-lateral volume-clamp device. Measurements by the device under test are performed in the contra-lateral arm.

the current study introduced an additional comparator intended to verify the accuracy of the reference double-blinded auscultatory measurements: the finger volume-clamp measurement device[23] (Nexfin, BMEYE BV, The Netherlands). Volume-clamp has been repeatedly been shown to be unaffected by vasomotion effects induced by body position changes and physical exercise[24–26] and appears to be a more reliable reference BP monitoring method under such conditions. It is important to note that the current study introduced volume-clamp to assess the reliability of a BP trend as seen by auscultation at each episode of a body position change (*i.e.* assessing the difference between two consecutive measurements), but was not used to assess the accuracy of BP readings (*i.e.* comparing absolute values of BP from both measurement modalities).

Data analysis. *Reference-control of auscultation readings by volume-clamp.* For each assessment, an auscultation reference value was computed as the average value between the readings of the two observers (following the guidance of ISO81060-2[27] as described in[19]). Furthermore, for those assessments that were not performed in the standard sitting-setting and relaxed conditions, the reliability of auscultation readings was controlled using a volume clamp. The reference-control was performed as follows: if a BP change as measured by the two modalities (auscultation versus volume-clamp) was detected in agreement (in the same direction) and differed less than 10 mmHg, the auscultatory BP reference value was retained for further analysis. Otherwise, the reliability of auscultation was considered unsatisfactory, and the assessment was rejected. This reference-control procedure is illustrated in Step 1 of Fig. 4. Note that volume-clamp BP readings are not further treated as an independent set of reference values for this study: their use is restricted to the reference-control process described in this section.

From the optical signals to calibrated BP values. For each assessment that was retained for further analysis, the raw optical signal recorded by the Aktiia Bracelet was analyzed by Aktiia algorithms to generate one uncalibrated SBP value and one uncalibrated DBP value. The generation of uncalibrated BP values was performed based on the principle of Pulse Wave Analysis as described in[28,29]. Assessments with optical signals depicting insufficient quality (due to movement artifacts or reduced skin perfusion) were automatically discarded by Aktiia algorithms and not retained for further analysis as described in[29] (Fig. 4, step 2). Finally, uncalibrated SBP and DBP values were transformed into calibrated BP values as described in[19].

Statistical analysis. To evaluate the ability of the Aktiia Bracelet to generate BP values for measurement conditions occurring in real-life scenarios, the percentage of assessments for which the recorded optical signals could be analyzed by the Aktiia algorithms was calculated for each measurement condition (acceptance rate index).

To provide performance figures of the Aktiia Bracelet when used in a sitting and relaxed condition, reference auscultatory values were compared against Aktiia readings according to criterion 1 and criterion 2 of ISO 81060-2 (as reported in[19]). These are the same criteria used in the validation of automated oscillometric cuffs in the same standardized sitting measurement conditions. For all the other measurement conditions, performance figures of the Aktiia Bracelet were calculated as the mean and the standard deviation of the differences between Aktiia Bracelet readings and auscultatory values (no pass/fail criterion from ISO81060-2 is applicable for these non-standard measurement conditions).

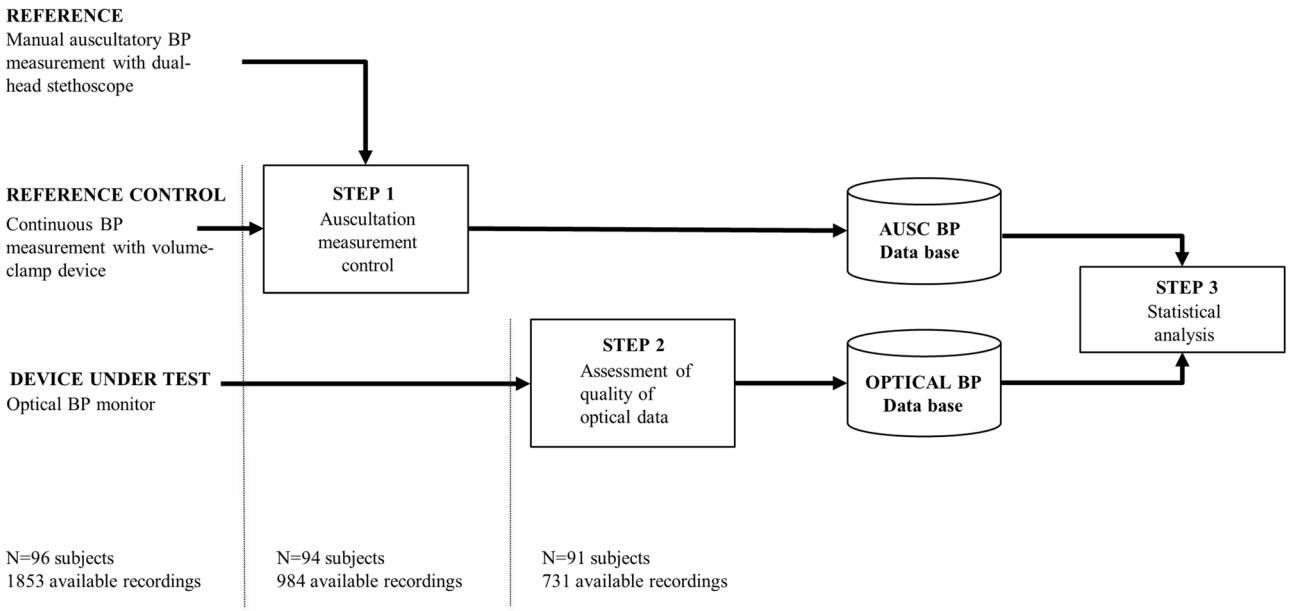


Figure 4. Implemented data analysis controlling the reliability of auscultatory BP measurements by means of a reference control (volume-clamp measurements), and further identifying assessments for which quality of optical signals is sufficient to execute Pulse Wave Analysis routines of the algorithms of Aktiia Bracelet. The number of available subjects and recording at each step is reported.

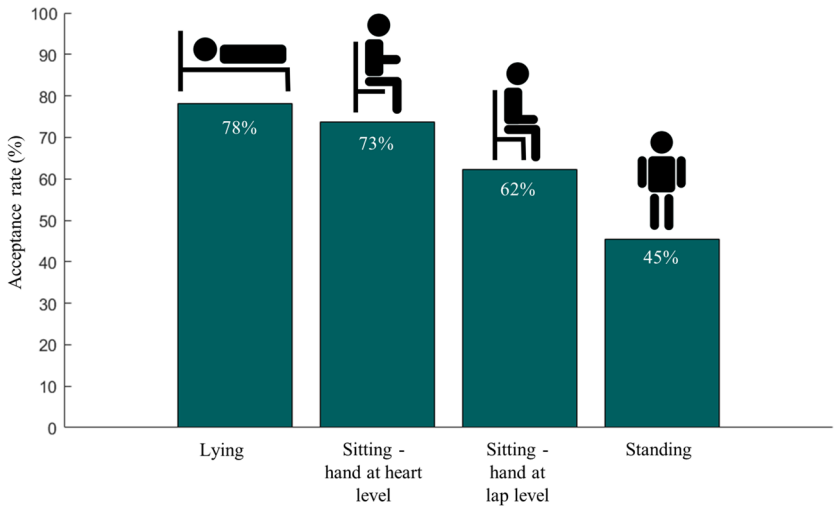


Figure 5. Acceptance rate of the Pulse Wave Analysis algorithms of Aktiia bracelet for each body position: percentage of time for which the recorded optical signals could be analyzed to generate a SBP and a DBP value.

Scatter plots, correlation coefficients and Bland Altman plots comparing reference auscultatory values against Aktiia readings were generated for all measurement conditions following the guidelines of AAMI/ESH/ISO[30].

Results

After performing the data processing steps described in Fig. 4, a total of 731 paired BP measurements from 91 participants were retained for further analysis.

The acceptance rates (percentages of retained measurements) for each measurement condition are reported in Fig. 5. For lying and sitting positions, the Aktiia Bracelet could generate BP estimates from the optical signals more than 70% of the time. When the wrist equipped with the bracelet was lowered to the lap level in the sitting position (around 50 cm below heart level), the acceptance rate decreased to 62%. The lowest acceptance rate was observed on standing position (45%).

For all measurement conditions, the mean and standard deviation of the differences between the two measurement modalities are reported in Table 2. In terms of precision, the lying and standing positions were associated

	N readings	Systolic blood pressure			Diastolic blood pressure		
		Accuracy	ISO81060-2		Accuracy	ISO81060-2	
		Mean ± Std (mmHg)	Criterion 1	Criterion 2	Mean ± Std (mmHg)	Criterion 1	Criterion 2
Sitting—wrist at heart level	335	0.46 ± 7.75	PASS	PASS	0.39 ± 6.86	PASS	PASS
Sitting—wrist at lap level	177	− 3.02 ± 6.10	N/A	N/A	− 4.22 ± 6.56	N/A	N/A
Lying	146	− 2.44 ± 10.15	N/A	N/A	− 1.93 ± 7.65	N/A	N/A
Standing	73	− 0.62 ± 12.51	N/A	N/A	− 4.85 ± 9.11	N/A	N/A
All positions	731	− 1.11 ± 9.85	N/A	N/A	− 1.32 ± 7.56	N/A	N/A

Table 2. Performance of the Aktiia Bracelet when compared against double auscultation for different body positions. Results depict mean and standard deviation of the differences between the two measuring modalities, and pass/fail criteria of ISO81060-2 when applicable[19].

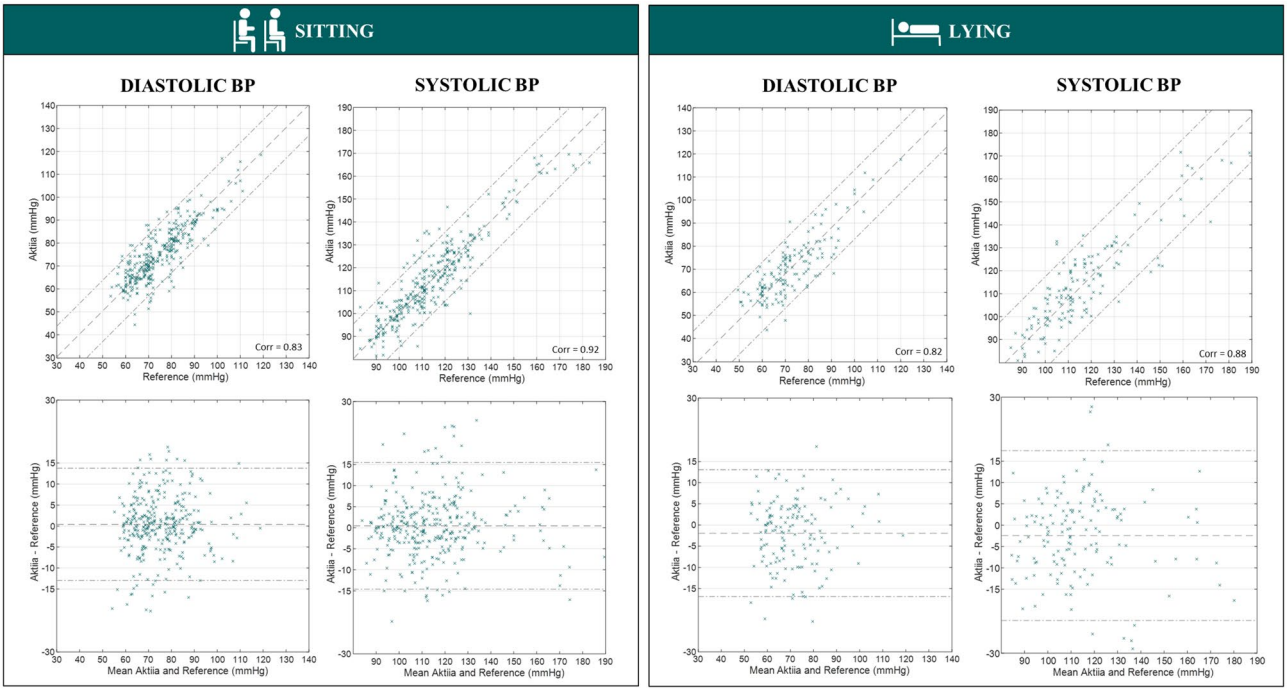


Figure 6. Scatter plots and Bland Altman plots comparing Aktiia BP readings against reference auscultatory readings for sitting and lying positions.

with the largest standard deviations for both systolic and diastolic BP readings. It is important to highlight the fact that the bias between both methods (measured as the average of the differences) did not significantly change when moving the wrist from the level of the heart to the level of the lap level in the sitting position. As already reported in[19], for the sitting and relaxed position for which ISO81060-2 performance criteria are applicable, the obtained results meet criterion 1 and criterion 2 of the standard.

Finally, the scatter plots and standardized Bland–Altman plots for SBP and DBP for all measurement conditions are illustrated in Figs. 6 and 7.

The participants reported that BP measurement with the Aktiia Bracelet was unnoticed and rather enjoyable compared to the traditional auscultatory method.

Discussion

In this study, we demonstrated that the Aktiia bracelet is capable of generating BP readings across different motionless conditions, with high probabilities of generating readings in sitting and lying positions. In a sitting position, when the wrist is lowered to the lap level, a decreased acceptance rate is observed most likely due to a reduced arterial pulsatility induced by increased congestion of venous blood. In a standing position, even by asking patients to be static, movement artefacts most likely are the cause of a lower acceptance rate: it is important to highlight that under motion the device automatically aborts a measurement. In the context of the use of 24-h ABPM recordings in clinical practice, the historical consensus is that at least 70% of the expected recordings is

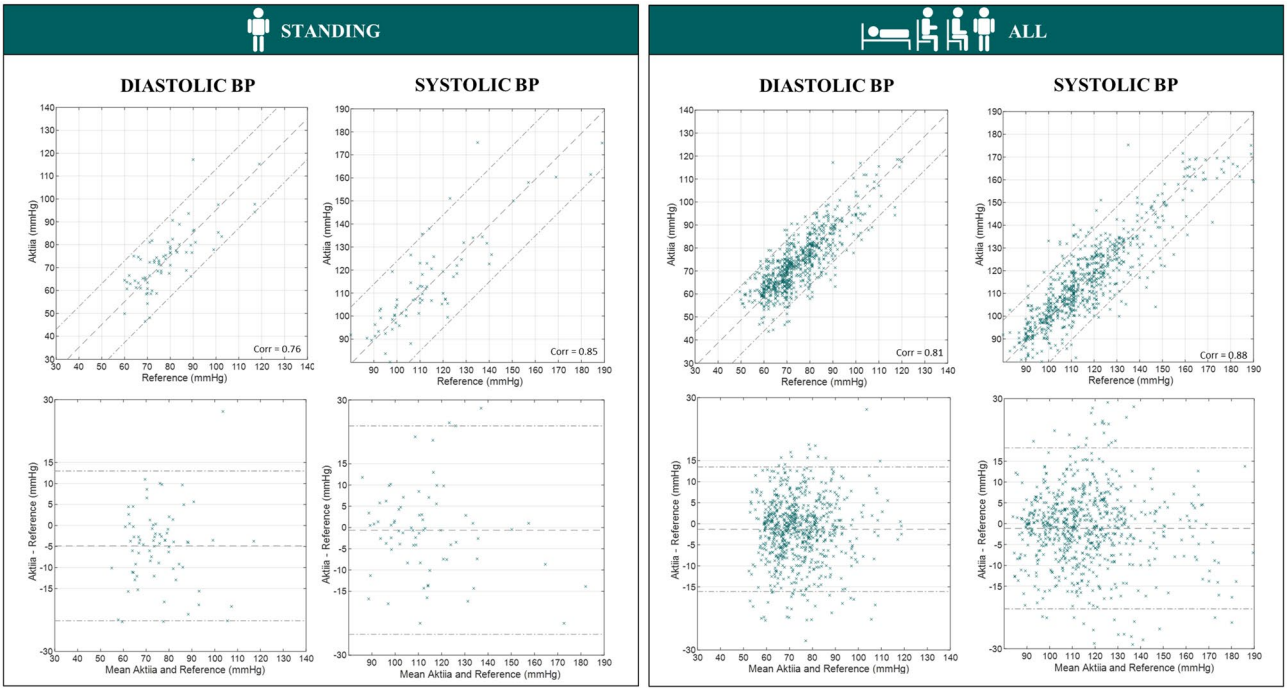


Figure 7. Scatter plots and Bland Altman plots comparing Aktiia BP readings against reference auscultatory readings for standing and all positions.

required for an ABPM exam to be considered satisfactory[31]. While the acceptance rates reported by this study are lower than 70% for some body positions, the fact that wearable BP devices will be used for longer periods mitigates for this reduced performance: wearable BP monitors enable the first-ever persistent monitoring of BP, allowing to capture enough readings in each body position over days and weeks (as opposed to only 24 h by cuff-based ABPM monitors). It is still worth mentioning that another major difference between an ABPM device and a wearable BP monitor is that while the first requires subjects to be still during a reading to avoid measurement errors and automatically repeats failed attempts, the second doesn't have such capability. Consequently, during long periods of movement, a wearable BP monitor will most certainly provide less BP readings than an ABPM device on a 24-h basis.

For the sitting position, this study demonstrated good accuracy of SBP and DBP readings from the Aktiia bracelet when compared to auscultatory measurements irrespectively of the position of the arm during the recording. The fact that the bias between both methods did not significantly change when lowering the wrist of the Aktiia Bracelet from the level of the heart down to the level of the lap confirms previous findings[32] and supports the hypothesis that the BP values generated by Aktiia Bracelet are not affected by the hydrostatic drop between the heart and the wrist. Indeed, if Aktiia BP values were affected by hydrostatic gradients, the bias of this experiment would increase by + 20 mmHg (corresponding to the hydrostatic pressure drop of a standard individual between the heart and the laps). This finding is crucial for the introduction of persistent BP measurements in real-life conditions: because BP readings are not dependent on the position of the arm relative to the heart, the Aktiia Bracelet can automatically trigger measurements without the user being aware of it and removes constraints of cuff-based measurements for which the user needs to position the arm in a particularly controlled posture and then manually trigger a measurement.

For the standing and lying positions, this study demonstrated that the difference of readings between Aktiia and auscultation present larger spreads than for the sitting position. These results can be explained by the combination of two effects. First, the Aktiia Bracelet was initialized for each patient in the sitting position. By evaluating the performance on other positions, the pulse wave analysis algorithms might be prone to introduce position-dependent calibration bias. Second, the reliability of auscultatory measurements in other conditions than sitting and relaxed is not guaranteed. Although we discarded highly unlikely auscultatory measurements through a reference-control procedure, a significant source of uncertainty in the reference readings remains in this dataset. All in all, most of the assessed precisions remain below (or close to) 10 mmHg, even in such challenging real-life conditions. It is important to note that there is no international standard or consensus that covers the validation of BP monitors in such real-life conditions and that even current devices used in clinical practice for ABPM are not validated in such standing or lying body positions. In addition, it is worth highlighting that the study did not implement the additional requirements of ISO81060-2 standard[27] for testing BP monitors intended for use in ambulatory monitoring. Unlike ABPM devices, the Aktiia Bracelet does not effectively perform measurements when the arm of the person is in motion, or while performing aerobic exercise, or not even several seconds after having stopped any physical activity: by design, the Aktiia Bracelet performs measurements only when subjects are quiet with the arm still and therefore, exercise-related validation requirements are not applicable.

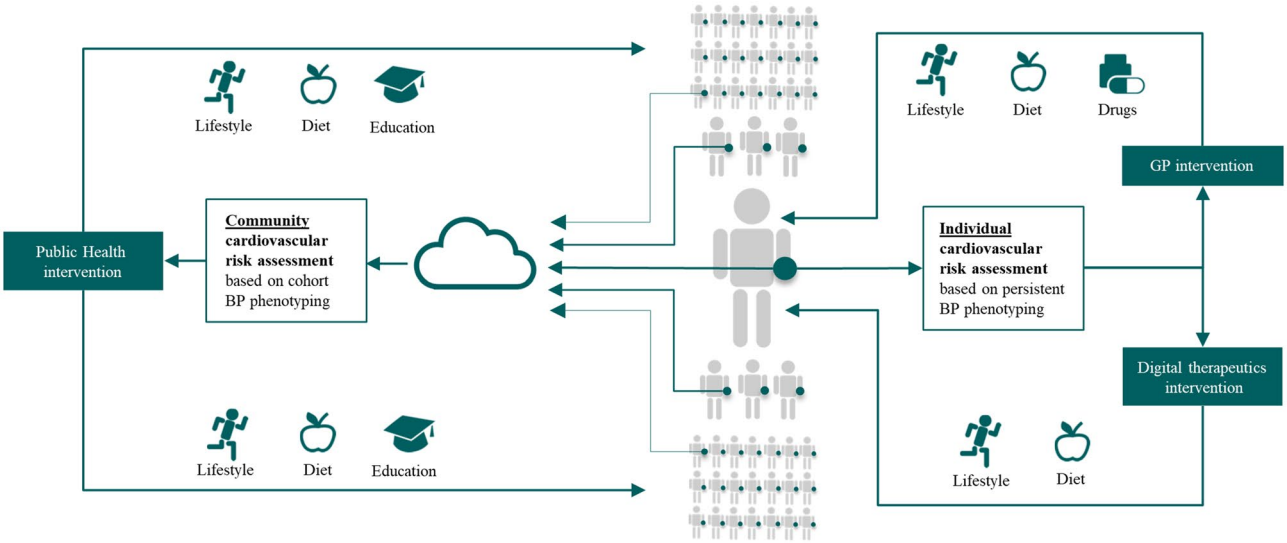


Figure 8. Introduction to the concept of BP phenotyping using persistent BP monitoring at the wrist, enabling a new category of studies and programs to investigate how longitudinal 24/7 measurements can improve cardiovascular outcomes at both individual and community levels.

As it has already been explained, out-of-office BP measurements are better predictors of cardiovascular events and are recommended by the most recent international guidelines. In particular, the nighttime measurements and the decrease in BP during the nighttime, called night dip, are known to be the best predictors of cardiovascular risk. Unfortunately, accurate out-of-office BP measurements still require the use of automated inflation cuffs, either for ABPM or HBPM procedures. The inflation of the cuff during measurement is known to trigger an increase in BP sometimes called cuff-inflation hypertension, and ABPM measurements during the night cause sleep arousal and stress, leading to higher BP readings[33]. Therefore, optical BP monitoring solutions that do not involve a cuff, hold a strong potential for 24 h BP monitoring, particularly for the nighttime measurements, and could allow better patient long term adherence to BP monitoring and reduced healthcare costs. Such devices do not involve an uncomfortable and painful cuff and could seamlessly blend into a patient's life and accompany the patient day and night.

In this study, we assessed the performances of such a cuffless monitor, the Aktiia Bracelet, against double-blinded auscultation. In the context of addressing the feasibility of daytime and nighttime measurements, we deemed it important to go beyond assessing the performance of the device in a sitting position and we extended the recommendations of ISO 81060-2 by testing the device in other body positions. Thus, we integrated a realistic scenario of daytime and nighttime monitoring into the experimental protocol. Aware of the limitations related to Korotkoff sounds detection when performing auscultation in positions other than sitting and relaxed, we added a reference-control device to discard potentially unreliable auscultatory measurements. To test the performances of the device in a representative cohort of the intended population, we included male and female patients, with the BP values ranging from hypotensive to hypertensive as required in the ISO 81060-2 international standard. Besides, we deemed it important to address whether the quality of the optical signals recorded by the Aktiia Bracelet would compromise the reliability of the pulse wave analysis algorithms in patients with darker skin pigmentation (due to the increased absorption of the light), as well as in patients with increased hair follicle density (due to the introduction of an optical barrier). Finally, to assess the stability of the calibration, we extended the experimental protocol over 1 month. To the best of our knowledge, no other ambulatory or wearable BP monitor has disclosed results in this direction with such a complete experimental protocol and such a large and diverse cohort.

Outlook and perspectives

This study provided an objective assessment of the accuracy that cuffless optical BP monitors can achieve when generating systolic and diastolic BP readings for the different body positions of 24/7 scenarios. It is important to note that for some body positions the differences between cuffless BP readings and simultaneous auscultatory BP readings were observed to deviate from the requirements that the ISO81060-2 defines for the sitting position. However, we hypothesize that the benefit of persistently monitoring the BP of a patient (as opposed to intermittent measurements at specified intervals) may outweigh possible deviations from an accuracy requirement that is not even tested or required under current regulations and unknown for existing devices for body positions such as standing or lying. This long-term risk–benefit ratio of such cuffless optical BP monitors is now to be assessed by means of cross-sectional and longitudinal epidemiological studies in order to test the association of persistent BP readings with target organ damage and cardiovascular events.

Moreover, if accurate, the benefit of persistent BP monitoring might go beyond a simple extension of sporadic BP measurements performed on-demand. This technology enables a new category of studies and programs that can investigate how longitudinal 24/7 measurements performed at large scale support the BP phenotyping of

individuals and communities. In this context, Fig. 8 provides a perspective on how persistent BP monitoring might extend and complement current existing BP monitoring modalities.

Firstly, on a patient level, the deployment of persistent BP monitoring in new clinical trials will enable to investigate how BP phenotyping services can be used to improve the assessment of individual cardiovascular risks and facilitate more targeted interventions. New digital therapeutic interventions and programs with or without GP involvement can be tested to dynamically quantify changes in individuals' BP phenotypes at each step of titration on lifestyle or diet interventions during those trials.

Secondly, on a public-health level, the deployment of persistent BP monitoring in large-scale clinical trials will enable investigation of how community-scale cardiovascular risk scores generated by pooling BP phenotypes of entire cohorts can be used to target specific communities to improve awareness on hypertension, or intervene on salt-content of the diet of given geographical regions, or encourage lifestyle changes on a given group of age or ethnic group of a particular city for example. The implementation of such large-scale clinical trials could also be supported by different types of smartwatches and smart bands that integrate validated optical BP monitoring capabilities.

In summary, the impact of the dynamic cardiovascular risk assessment of individuals and communities that will be supported by the persistent BP monitoring at the wrist is yet to be quantified, but its potential is promising.

Conclusion

This study has provided a first objective assessment of the performance of a wearable persistent BP monitor in different body positions. Because of its ease of use, wearable BP monitors have the potential to enable 24 h BP phenotyping of patients over long periods, and if deployed at a community level they may be also useful to drive public health interventions to detect and control hypertension.

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Author contributions
A.V., J.S., and G.W. conceived and designed the study. A.W. and E.P. took charge of the participants and collected data that were further analyzed by J.S., A.V., S.F., and G.W. Finally, J.S., G.W., A.V., and S.F. prepared the manuscript. All authors reviewed the manuscript.

Competing interests
J.S., A.V. and S.F. are employees of Aktiia SA. G.W. serves as a consultant for Aktiia SA. All other authors report no potential conflicts of interest.

Additional information
Correspondence and requests for materials should be addressed to J.S.

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