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Unattended versus attended blood pressure measurement: Mean values and determinants of the difference☆,☆☆

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1. Introduction

The relationship between blood pressure (BP) values and the risk of cardiovascular (CV) events and mortality is continuous, and extends to values well below the traditional thresholds for the definition of hypertension. Available data clearly indicate that raised BP represents the most important single contributor to the global burden of disease and to global mortality worldwide [1–5]. The results of clinical trials and meta-analyses have clearly shown that pharmacological reduction of BP values is highly effective in reducing CV events and mortality. For all these reasons, accurate measurement of BP values is particularly important for CV prevention. Current European hypertension guidelines recommend measurement of BP in the physician's office as the standard approach for the diagnosis of hypertension and for the guidance of antihypertensive treatment, in view of the large and robust data collected in decades of randomized clinical trials. The technique is very similar to the one described by Scipione Riva-Rocci one century ago, and has several limitations. Indeed, the variability of blood pressure values and the well-known "white coat effect" represent major drawbacks of this approach [6–9]. In most Countries, in recent years, due to environmental issues, automated or semiautomated oscillometric devices for BP measurement have progressively replaced mercury sphygmomanometers. These devices have several advantages and also allow measurement of BP in the absence of the physician, both in the clinic and at home, thus making possible the so called "automated office BP measurement" (AOBP), in which multiple automated readings are performed using an electronic device with the patient sitting alone in the office [8, 9]. This type of measurement, which has also been described as "unattended blood pressure measurement" [10], has been used in the majority of patients enrolled in SPRINT (Systolic Blood Pressure Intervention Trial) [11, 12], as reported by Johnson et al. [13]. Very recently some international hypertension Guidelines [14, 15] have suggested that this approach could be preferable over conventional BP measurement, also because some previous studies have suggested that this approach could be less influenced by the alerting reaction induced by the presence of the medical staff, and correlates closely with ambulatory BP and organ damage [16–19]. On the other hand, very few data are available on the prognostic significance of unattended BP; the results of a study in which BP was measured with the BpTRU device in pharmacies in Ontario demonstrated a direct correlation between BP and CV events; the study, however, did not assess the superiority of unattended BP over attended BP [20]. Furthermore, despite the possible advantages of the "unattended" approach for BP measurements, several Authors have raised doubts about the interchangeability of the results obtained with the two approaches [21–23]. Very few properly designed studies have compared the two BP measurements, often used different approaches and therefore led to conflicting results [24–26].

We considered it worthwhile to compare BP values obtained by the unattended approach to those obtained in the same environment in the presence of the physician, using the same automated oscillometric device.

2. Methods

Three hundred twenty-nine consecutive outpatients undergoing a visit at the ESH Excellence Centre in Brescia (Italy) were prospectively included in the study. All patients

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underwent a through clinical examination, including anthropometric measurements. CV risk factors were carefully assessed for each individual, and a documented clinical history was collected, including diabetes, smoking status and pharmacological treatments. All individuals were in a fasting state, refrained from alcohol and caffeine-containing beverages. The procedures followed were in accordance with institutional guidelines, and informed consent was obtained from each patient. The study protocol was in accordance with the ethical guidelines of 1975 the Declaration of Helsinky, and approved by the Institution's Human Research Committee.

2.1. Blood pressure measurement

BP values were measured according to a standardised protocol by a physician in a controlled environment at 22 ± 1 °C, at the upper arm, with cuff and bladder dimensions adapted to the arm circumference with an automated oscillometric device (Omron HEM 9000Ai). All patients underwent "unattended" BP measurement (the patient was left alone in the room, and the oscillometric device was programmed to automatically perform 3 BP measurements with 1 min intervals between recordings after 5 min of rest). All patients also underwent attended BP measurement as follows: the physician was sitting in front of the patient and, after 5 min of rest, activated the device that automatically measured BP three times at 1 min intervals; the physician did not interact with the patient during all this time lapse. The unattended and attended measurements were performed in a random order with the same oscillometric device. For both BP measurements, SBP and DBP were calculated as the mean of three consecutive readings.

2.2. Statistical analysis

All data are expressed as mean ± SD. Relationships between variables were assessed by the calculation of Pearson correlation. Attended and unattended BP values were compared using Bland–Altman plots. A stepwise multivariate regression analysis was then performed; the dependent variable was the differences (Δ) between attended and unattended values. All statistical tests were two-tailed. A value of $p < 0.05$ was considered statistically significant. All analyses were performed with IBM SPSS software (version 23; SPSS Inc., Chicago, IL) and MedCalc for Windows, version 15.0 (MedCalc Software, Ostend, Belgium).

3. Results

Demographic characteristics and the prevalence of cardiovascular risk factors of all patients included in the study are detailed in Table 1. The mean age was 61 ± 15 years, 60% of all patients were males, 93% were hypertensive and, among them, 39% were untreated and 61% were treated, with dihydropyridinic calcium channel blockers, β-blockers, angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, and diuretics. As compared to males, female patients were older (63 ± 14 vs 59 ± 16 years, $p < 0.05$) and had significantly higher SBP values (142 ± 19 vs 136 ± 14 mmHg, $p < 0.001$). The prevalence of dyslipidaemia and diabetes were 51.5 and 12.5%, respectively.

Systolic unattended BP was lower as compared to attended SBP (129.8 ± 15.5 vs 138.4 ± 16.7 mmHg); also unattended DBP was lower than attended (77.3 ± 11.4 vs 79.3 ± 11.9 mmHg)(Fig. 1). The

Table 1
Demographic and clinical characteristics of the population.

	$N = 329$ patients
Age (years)	61 ± 15
Sex (males/females) (%)	196/133 (59%,41%)
Height (cm)	170 ± 9
Weight (kg)	75 ± 15
BMI (kg/m^2)	26 ± 4
Hypertension, n (%)	306 (93%)
Antihypertensive treatment (%)	202 (61%)
Diuretics, n (%)	95 (47%)
β-blockers, n (%)	97 (48%)
CC-blockers, n (%)	91 (45%)
ACE-i or ARB, n (%)	161 (79.7%)
Potassium-sparing diuretics, n (%)	22 (10.9%)
α-blockers, n (%)	42 (20.8%)
Dyslipidaemia, n (%)	169 (51.5%)
Diabetes, n (%)	41 (12.5%)
Smoking (no/yes/ex) (%)	198 (60%)/49 (15%)/82 (25%)

CC-blockers: Dihydropyridinic calcium channel blockers; ACE-i: Angiotensin-converting enzyme inhibitors; ARB: Angiotensin receptor blockers.

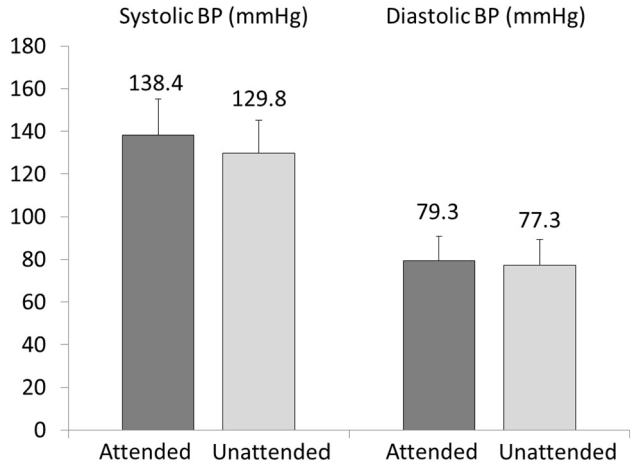

Fig. 1. Attended and unattended Systolic and Diastolic BP values (mmHg) in the whole population.

coefficient of correlation between the two methods was $r = 0.887$ ($p < 0.0001$) for systolic values and $r = 0.902$ ($p < 0.0001$) for diastolic values.

The differences (Δ) between the values obtained using the two approaches were 8.6 ± 7.7 mmHg for SBP and 2.0 ± 5.2 mmHg for DBP. Δ SBP was directly correlated with age ($r = 0.211$, $p < 0.0001$), and with attended BP values ($r = 0.384$, $p < 0.0001$). Δ SBP was significantly lower in males than in females (7.5 ± 6.9 and 10.1 ± 8.6, $p < 0.005$). No difference was observed between treated and untreated patients: Δ SBP was 8.3 ± 8.1 in untreated and 8.7 ± 7.5 in treated (p ns), Δ DBP was 1.9 ± 4.6 in untreated and 2.1 ± 5.5 in treated patients (p ns). Furthermore, no difference was observed between diabetic and non-diabetic patients: Δ SBP was 8.5 ± 7.9 in non-diabetics and 9.6 ± 6.9 in diabetics (p ns), Δ DBP was 2.1 ± 5.3 in non-diabetics and 1.7 ± 4.5 in diabetics (p ns).

Δ DBP was directly correlated with attended DBP ($r = 0.322$, $p < 0.001$), but not with age and sex.

In this population, the relationship between attended and unattended SBP is described by the following equation: $y = 0.8929 * x + 3.5714$; where y is unattended SBP and x is attended SBP; accordingly, attended SBP value of 140 mmHg corresponded to an unattended SBP of 129 mmHg (Fig. 2).

When a multivariate analysis was performed, including in the model age, sex and attended SBP, Δ SBP remained independently correlated with age (beta 0.146, $p < 0.01$) and attended SBP (beta 0.346, $p < 0.001$), while sex did not enter in the model; therefore, we derived from regression analysis the equation estimating unattended SBP values including attended SBP and age:

$$y = 0.840^{*}x - 0.073^{*}age + 17.279$$

where y is unattended SBP, x is attended SBP and age is expressed in years.

In Fig. 3 are reported Bland-Altman plots showing the differences between attended and unattended SBP (panel A) and DBP (panel B) values. The limits of agreement were wide, being −6.6 to 23.7 mmHg for SBP and −8.2 to 12.2 mmHg for DBP, respectively.

4. Discussion

The results of our study suggest that BP values obtained by the unattended approach are lower as compared to those obtained in the presence of the physician. In fact, unattended systolic BP was 8.6 mmHg lower as compared to attended systolic BP; unattended diastolic BP was 2.0 mmHg lower as compared to attended diastolic BP.

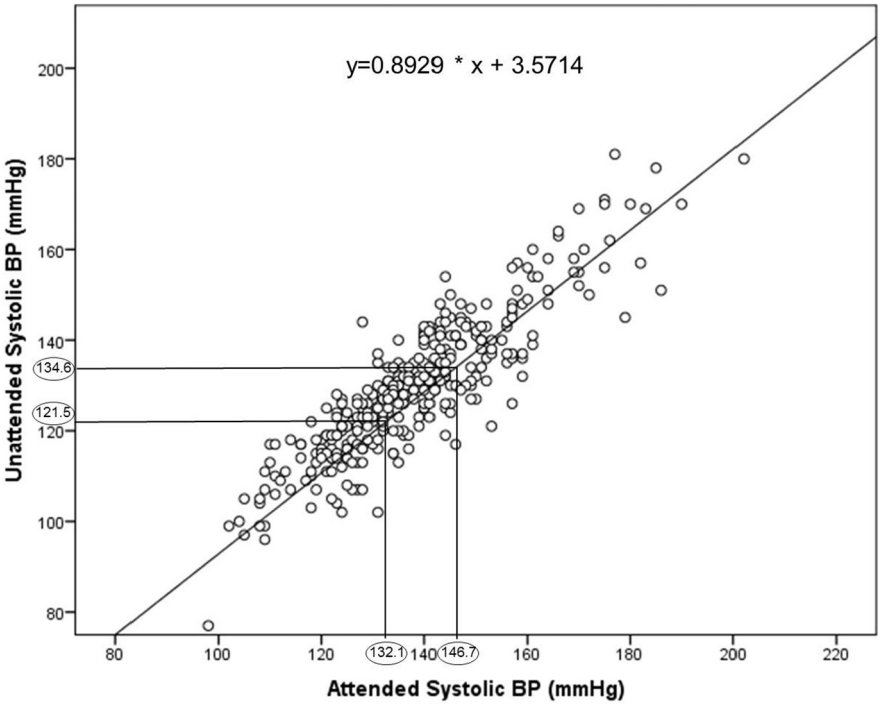

Fig. 2. Relationship between attended systolic BP and unattended systolic BP. The horizontal and vertical lines indicate the attended systolic BP values estimated to correspond to the unattended BP values in SPRINT.

In this group of patients, BP measurements were performed with the same validated, and completely automated oscillometric device; furthermore, unattended BP was measured with the same approach used in a large proportion of the patients enrolled in SPRINT (patients left alone in a quiet room, 3 recordings with an automated device after 5 min of rest), thus allowing a direct comparison between BP values obtained in SPRINT and those obtained in the physician's office during the visit according to current European hypertension guidelines [6]. Filipovský [25] described a difference of −15 mmHg for systolic and of −8 mmHg for diastolic BP when using the automated unattended approach. The protocol used by Filipovský for unattended BP measurement was significantly different from the one we used, possibly explaining the smaller difference between attended and unattended BP values observed in our study. In fact, in the study by Filipovský the mean of the second to the sixth of six measurements was used, the patient was asked to activate manually the device after 5 min of rest. Furthermore, attended BP was measured by the auscultatory technique and the number of measurements was not standardised, ranging from 1 to 3, thus introducing possible biases influencing the comparison between the two approaches.

Recently, in another study in 275 hypertensive patients with chronic kidney disease, Agarwal reported a mean difference of 12.7 mmHg for SBP and 8.7 for DBP when comparing attended and unattended measurements [24]. However, Agarwal measured attended BP only once in the supine position, thus making it difficult to compare the results with those obtained in our study and in clinical trials in which attended BP was measured according strict standardised protocols reflecting guidelines recommendations. Furthermore, in that study [24] BP was measured with the oscillometric technique but with two different devices (Omron HEM 705 CP and Omron HEM 907). Only few studies have compared unattended and attended BP using the same oscillometric device. Four of them [27–32] found little or no difference between attended and unattended BP values. At variance with these results, in a recent study by Filipovský and coworkers [33], the difference between attended and unattended BP in the subgroup of patients in which BP was measured with the same oscillometric device, was of 8.6/2.0 mmHg, which is very similar to that observed in our study. The characteristics of patients included in the studies, and in particular age, gender, mean BP values, the prevalence of smokers and the presence of a familiar medical environment (general practitioners/specialists) might in part explain the different results obtained so far, and also indicate that more research is needed.

In the recent analysis of the SPRINT results by Johnson and coworkers no differences in follow up BP values and in the reduction of CV events in the intensive BP lowering arm were observed between patients in whom BP was measured by the attended approach as compared to those in whom it was measured by the conventional approach. Despite the importance of these results for the interpretation of SPRINT, it should be kept in mind that the study does not provide direct information on the relationship between attended and unattended BP in the same patients, since both unattended and attended BP measurements were not made in the same individual participant at the same time.

Our findings support the concept that the interpretation of the SPRINT results should take into account the differences in BP values obtained by the two approaches [21–23]. In our population, the mean systolic BP value observed during treatment in the intensive and in the standard BP-lowering arm of SPRINT, i.e. 121.5 and 134.6 mmHg, corresponded to attended systolic BP values of 132.1 and 146.7 mmHg, respectively. Of note, the relationship between values provided by the two approaches is not constant, being the difference between the two types of measurement of 10.6 mmHg when attended BP is 121.5 mmHg and 12.1 mmHg when attended BP is 134.6. A significant linear correlation between Δ and attended BP values was, in fact, observed. In other words, at higher BP levels the difference between the two approaches is greater. Of note, similar results have been described for the difference between clinic BP and daytime BP values as assessed by ambulatory BP monitoring, where the difference is greater in the higher range of clinic BP distribution and becomes smaller at lower BP values [21, 34]. Blood pressure

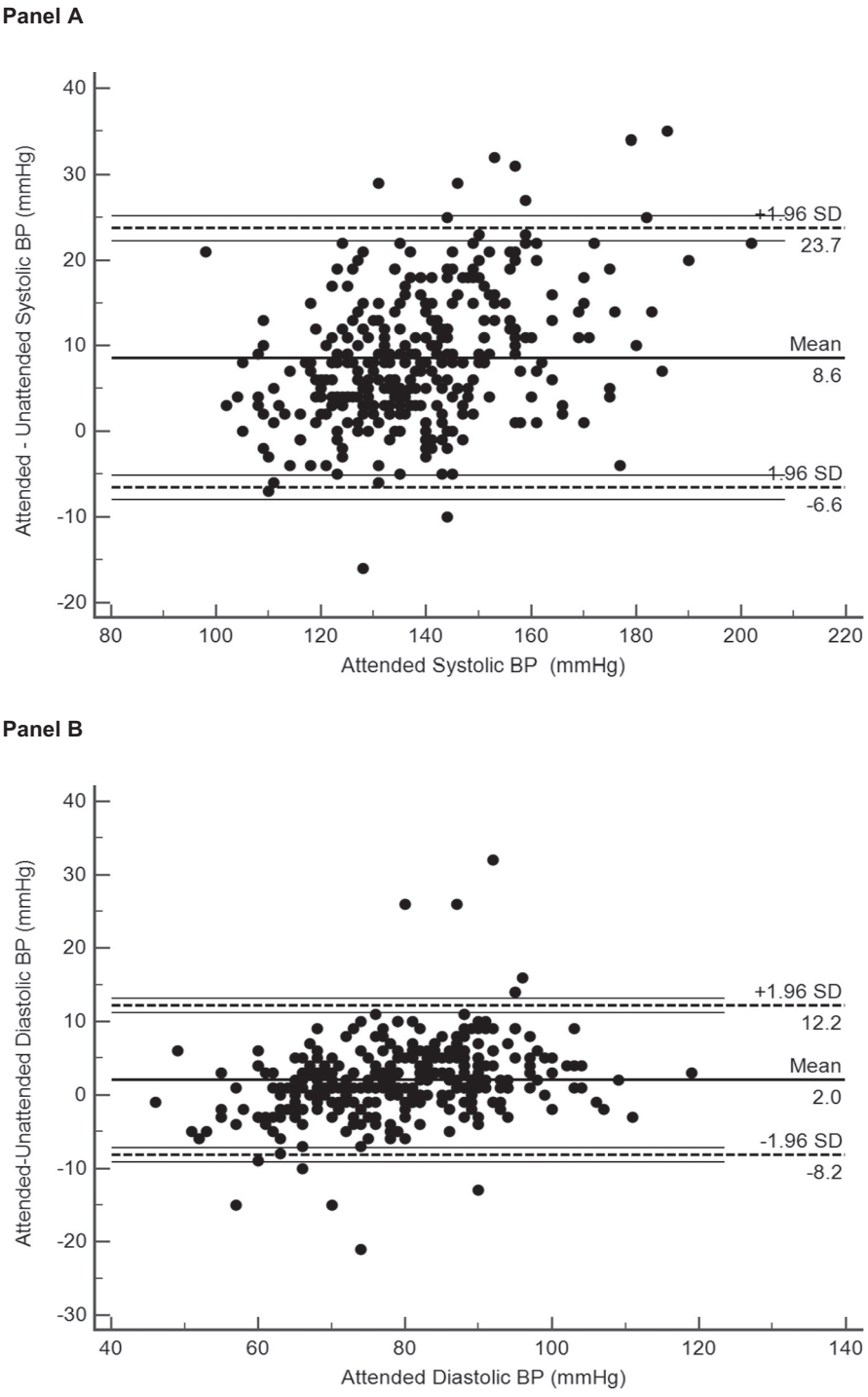

Fig. 3. Bland-Altman plots showing the differences between attended and unattended systolic (panel A) and diastolic (panel B) BP values.

values were not the only factors associated to the discrepancy between the two approaches, and also age and gender significantly influenced Δ BP. With increasing age, the difference between the values obtained with the two approaches increased, and a significant correlation between age and Δ SBP was also observed. Furthermore, Δ SBP was significantly lower in males than in females. The effect age and attended BP on the Δ SBP remained significant also at multivariable analysis, indicating a true contribution of these factors to the discrepancy between the two types of measurement. On the contrary, the difference between the two approaches for the measurement of DBP seems to be influenced only by attended DBP level.

Based on the results of our study, we derived a formula describing the relationship between attended SBP and unattended SBP, which could be of help when comparing BP values of the population of patients included in SPRINT to those obtained in other clinical trials. According to our data, the results of SPRINT would demonstrate lower rates of cardiovascular events (−25%) and all-cause mortality (−27%) in patients with an in-treatment estimated "attended" SBP value of 132 mmHg (intensive arm), as compared to those with an in-treatment estimated "attended" BP of 147 mmHg (standard treatment arm). These values are almost superimposable to those calculated by Parati et al. [21] (i.e. 127 and 147 mmHg, respectively), when they based their estimates

on the relationship between clinic and 24 h BP values in the ELSA Study and in SPRINT.

5. Limitations

When interpreting the results of our study it should also be considered that, at variance with SPRINT, we included only Caucasian subjects and that 12% of patients had diabetes mellitus; as in SPRINT, no patient had cerebrovascular disease. Therefore, our findings, and also the regression equation derived from our population should be used with caution when interpreting data from other populations.

In our study attended BP measurement was always performed by a physician; it could be worthwhile, in future studies, to analyze the relationship between unattended BP values and attended BP measured by non-physicians.

6. Conclusion

Our findings suggest that "unattended BP" measurement provides values significantly lower as compared to measurements obtained in the presence of the physician with the same oscillometric device. The difference between the values obtained by the two approaches is not constant for all patients, being significantly affected by age, gender and BP values. Our findings could be of help in the interpretation of the results of studies in which BP was measured with the "unattended" approach.

Conflict of interest

None.

Acknowledgments

None.

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