Impact of Atrial Fibrillation on the Accuracy of Oscillometric Blood Pressure Monitoring

Nikolaos Pagonas,* Sven Schmidt,* Jörg Eysel, Friederike Compton, Clemens Hoffmann, Felix Seibert, Justus Hilpert, Carsten Tschöpe, Walter Zidek, Timm H. Westhoff

Abstract—The introduction of automated oscillometric blood pressure monitors was the basis for today’s widespread use of blood pressure self-measurement. However, in atrial fibrillation, there is a controversial debate on the use of oscillometry because there is a high variability of heart rate and stroke volume. To date, the accuracy of oscillometric blood pressure monitoring in atrial fibrillation has only been investigated using auscultatory sphygmomanometry as reference method, which may be biased by arrhythmia as well. We performed a cross-sectional study in 102 patients (52 sinus rhythm, 50 atrial fibrillation) assessing the accuracy of an automated and validated oscillometric upper arm (M5 Professional, Omron) and wrist device (R5 Professional, Omron) to invasively assessed arterial pressure. Blood pressure values were calculated as the mean of 3 consecutive measurements. Systolic and diastolic blood pressure did not significantly differ in patients with sinus rhythm and atrial fibrillation, independent of the method of measurement (P>0.05 each). The within-subject variability of the oscillometric measurements was higher in patients with atrial fibrillation compared with sinus rhythm (P<0.01 each). The biases of systolic and diastolic blood pressure, however, did not significantly differ in presence or absence of atrial fibrillation in Bland-Altman analysis (P>0.05 each). In conclusion, atrial fibrillation did not significantly affect the accuracy of oscillometric measurements, if 3 repeated measurements were performed. (Hypertension. 2013;62:579-584.)

Key Words: atrial fibrillation ■ blood pressure measurement ■ hypertension ■ oscillometry ■ sphygmomanometers

The introduction of oscillometric automated blood pressure measurement devices has markedly simplified self-monitoring of blood pressure, and a lot of devices have proven sufficient accuracy in validation procedures according to the protocols of the British Hypertension Society, the European Society of Hypertension, or the Association for the Advancement of Medical Instrumentation.1–3 In contrast to sphygmomanometers, these devices do not detect Korotkoff sounds but the oscillations transmitted from the brachial or radial artery to the cuff. The pulse pressure curves are recorded, and an envelope curve is provided. Systolic and diastolic blood pressure levels are consecutively calculated by an algorithm.4 This method of blood pressure monitoring may be biased, however, by states of arrhythmia attributable to the high variability of heart rate and stroke volume. Most automated blood pressure monitors were validated and calibrated only for patients with sinus rhythm.5 Therefore, there is an ongoing controversial debate, whether oscillometric automated devices may be recommended in patients with atrial fibrillation (AF) or not. Even purchasers recommend caution when the devices are used in this setting.

Some isolated reports suggest that oscillometric automated blood pressure monitors and monitors that detect Korotkoff sounds electronically may provide a satisfactory level of accuracy in patients with AF.6–8 A recent meta-analysis indicated that oscillometric measurements can detect systolic, but not diastolic, pressure in a sufficiently accurate manner compared with auscultatory sphygmomanometry.9 However, in all previous reports, sphygmomanometry was used as reference technique. It has to be kept in mind that AF impedes sphygmomanometry as well because variations in stroke volume cause beat-to-beat differences in pulse pressure that in turn influence Korotkoff sounds. Therefore, the American Heart Association (AHA) stated in their Recommendations for Blood Pressure Measurements that intra-arterial blood pressure may be necessary to get a baseline for comparison.10 To date, however, these data are lacking. The present study puts this recommendation into practice for the first time. How does AF affect the accuracy of oscillometric devices? Is there a difference in the accuracy of upper arm and wrist devices in AF?

The present work investigates the accuracy of automated oscillometric blood pressure monitors in the presence and absence of AF using invasively assessed blood pressure as reference method.

Received March 20, 2013; first decision April 8, 2013; revision accepted July 5, 2013.
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© 2013 American Heart Association, Inc.
Hypertension is available at http://hyper.ahajournals.org DOI: 10.1161/HYPERTENSIONAHA.113.01426

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Methods

Protocol
We performed a cross-sectional study in 102 patients to assess the impact of AF on the accuracy of automated oscillometry using invasively measured blood pressure as reference method. To avoid an arterial access without medical indication, patients were recruited in an intensive or intermediate care setting. Inclusion criteria were presence of an intra-arterial catheter in the radial artery for continuous blood pressure monitoring, and written informed consent for participation. Exclusion criteria were hemodynamic or respiratory instability, use of vasoconstrictors, mechanical ventilation, aortic insufficiency more than or same as stage 2, a history of upper limb trauma or upper limb arterial stenosis, wrist circumferences <13.5 or >19.5 cm, inability to declare informed consent for participation, age <18 years. Optimal time point of examinations was the day of transfer to a peripheral ward before removal of the arterial line. All measurements took place in intensive or intermediate care units of the Charité at an ambient temperature of 20°C by the same trained observer. Invasive assessment of arterial pressure was performed by intra-arterial catheters in the radial artery as described below. All the patients were awake and rested in a supine position. We used an automated oscillometric upper arm device (M5 professional, Omron Medizintechnik, Mannheim, Germany) and an automated oscillometric wrist device (R5 Professional, Omron Medizintechnik, Mannheim, Germany). Noninvasive measurements were performed at the same arm as the invasive measurement. The study was approved by the Local Ethical Committee of the Charité–University Medicine Berlin, Germany.

Invasive Blood Pressure Measurement
The arterial catheter was inserted into the right or left radial artery (20-gauge BD Arterial Cannula, BD Critical Care Systems Pte Ltd, Singapore). Adjustment to atmospheric zero was performed before initiation of each measurement procedure by opening the transducer to atmospheric pressure. The monitoring system (Philips Hewlett Packard M1097A, Philips, Hamburg, Germany) provided intra-arterial blood pressure as an average over 12 heart beats. To have a stable intra-arterial measurement for baseline/reference values, the observer waited until 3 identical values were displayed on the monitor.

Oscillometric Blood Pressure Measurements
Before starting the noninvasive blood pressure measurements, upper arm and wrist circumferences were measured to allow correct choice of cuff size. To avoid venous congestion and to minimize variability in blood pressure, the time between measurements was determined to be 30 to 60 seconds. The M5 (identical to the M6 HEM-7001-E) has been validated according to European Society of Hypertension and British Hypertension Society protocol and was used according to manufacturer instructions.13,14 Moreover, the M5 underwent validation procedures for elderly and for obese patients.13,14 The R5 was validated by the Deutsche Hochdruckliga.15 Its standard cuff size is applied to wrist circumferences from 13.5 to 19.5 cm. Therefore, circumferences <13.5 or >19.5 cm were defined as an exclusion criterion. The wrist was placed at right atrial level beside the body with the patient lying in a supine position. Before the beginning of the measurements, the observer excluded palmar flexion or extension of the wrist.

Sequence of Measurements
Each of the 2 test devices was compared with invasively assessed blood pressure (reference) by 3 alternating measurements starting with the invasive assessment of blood pressure as the following examples:

1. Invasive assessment of blood pressure
2. Test device 1
3. Invasive assessment of blood pressure
4. Test device 1
5. Invasive assessment of blood pressure
6. Test device 1

The M5 was test device 1. The procedure was repeated using the R5 as test device 2. Thus, an overall number of 6 intra-arterial measurements were performed in each patient. The order of test devices remained unchanged through the study.

Study Population
We enrolled 102 consecutive patients, of which 52 patients (51.0%) had sinus rhythm, 50 patients (49.0%) suffered from AF at the time of the measurement procedure. Mean age was 67.6±14.1 ranging from 20 to 97 years. At the time point of the measurement, however, each patient was respiratorily and hemodynamically stable without respiratory and vasopressors. Table 1 provides a characterization of the study population, including epidemiological data, reason for current stay at the intensive/intermediate care unit, and concomitant diseases.

Statistics
Results are presented as mean±SD. Blood pressure values are the mean of 3 consecutive measurements. The performance of the different blood pressure measurement techniques was analyzed using 2 different approaches: (1) Assessment of bias and limits of agreement (bias±2×SD) by Tukey mean-difference plots (Bland–Altman plots) and (2) assessment of intraindividual variability. The bias was the difference of the blood pressure of each of the 3 noninvasive measurements and the intra-arterial blood pressure (reference technique). Comparison of numeric data of patients with and without AF was performed by unpaired 2-tailed ttests. Dichotomous parameters were compared by χ2 test (Fisher exact test for independent samples, McNemar test for dependent samples). P<0.05 was considered significant.

Results
We enrolled 102 patients, 50 of whom had AF (49.0%). As presented in Table 1, the patients in the 2 groups did not differ significantly concerning age, sex, body mass index, and reason for admission to an intensive care unit (P>0.05 each). Among the concomitant diseases, there was no difference in the prevalence of intermittent claudication, diabetes mellitus, end-stage renal disease, and hyperlipidemia. Hypertension, coronary heart disease, history of stroke, and congestive heart failure were significantly more prevalent in the patients with AF (P<0.05). The wrist device failed to provide results in 3 of 52 patients with sinus rhythm and 4 of the 50 patients with AF. The failure rates of 5.8% and 8% did not significantly differ between the 2 groups (P>0.05). The reason for these failures was the inability to place the cuff because of the arterial catheter or an intravenous cannula (2 patients in each group) or appearance of error message in 1 patient with sinus rhythm and 2 patients with AF. Invasive blood pressure measurement was successful in all but 1 patient. The upper arm oscillometric device was successful in all patients.

The mean invasively assessed blood pressure was 130.8±20.9 mm Hg systolic and 60.5±12.2 mm Hg diastolic (n=6 measurements per subject, n=606 in study population). The mean heart rate was 86.9±16.8 min⁻¹ in the group with sinus rhythm and 88.5±18.2 min⁻¹ in the group with AF (P<0.05). The systolic and diastolic blood pressure values measured with each of the 2 techniques did not significantly differ between patients with sinus rhythm or AF (P>0.05 each; Table 2). Table 2 presents the systolic and diastolic bias of each measurement technique for patients with and without AF compared with intra-arterial blood pressure. The Figure shows the Tukey mean-difference plots separated for sinus rhythm and AF. Both measurement techniques revealed no significant difference of the systolic bias in patients with sinus
rhythm and AF ($P>0.05$ each; Table 2). Accordingly, there was no significant difference in the bias of diastolic blood pressure in patients with sinus rhythm and AF either ($P>0.05$ each; Table 2). Both measurement devices had a negative bias of systolic blood pressure indicating an underestimation of the intra-arterial systolic pressure (Figure A; Table 2). The positivity of the diastolic bias indicates that both oscillometric techniques overestimated diastolic pressure (Figure B; Table 2). The systolic and diastolic within-subject (intra-individual) variabilities of the oscillometric techniques were significantly higher in patients with AF compared with those with sinus rhythm (Table 2; $P<0.05$ each).

The positivity of the diastolic bias indicates that both oscillometric techniques overestimated diastolic pressure (Figure B; Table 2). The systolic and diastolic within-subject (intra-individual) variabilities of the oscillometric techniques were significantly higher in patients with AF compared with those with sinus rhythm (Table 2; $P<0.05$ each).

### Table 1. Characterization of the Study Population

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Overall Study Population (N=102)</th>
<th>Sinus Rhythm (n=52)</th>
<th>Atrial Fibrillation (n=50)</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>67.6±14.1 (20–97)</td>
<td>64.9±14.2</td>
<td>70.3±13.6</td>
<td>0.06</td>
</tr>
<tr>
<td>Male</td>
<td>62 (60.8%)</td>
<td>29 (55.8%)</td>
<td>33 (66.0%)</td>
<td>0.32</td>
</tr>
<tr>
<td>Female</td>
<td>40 (39.2%)</td>
<td>23 (44.2%)</td>
<td>17 (34.0%)</td>
<td></td>
</tr>
<tr>
<td>Body mass index (kg/m$^2$)</td>
<td>27.7±6.3</td>
<td>26.9±6.2</td>
<td>28.4±6.4</td>
<td>0.24</td>
</tr>
<tr>
<td>Reason for current stay on the intensive care unit</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>21 (20.6%)</td>
<td>10 (19.2%)</td>
<td>11 (22.0%)</td>
<td>0.81</td>
</tr>
<tr>
<td>Sepsis</td>
<td>14 (13.7%)</td>
<td>7 (13.5%)</td>
<td>7 (14.0%)</td>
<td>0.77</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>14 (13.7%)</td>
<td>8 (15.4%)</td>
<td>6 (12.0%)</td>
<td>0.78</td>
</tr>
<tr>
<td>Observation after surgery</td>
<td>14 (13.7%)</td>
<td>7 (13.5%)</td>
<td>7 (14.0%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Heart failure</td>
<td>11 (11.2%)</td>
<td>5 (10.0%)</td>
<td>6 (12.5%)</td>
<td>0.76</td>
</tr>
<tr>
<td>Neurological disorders</td>
<td>9 (8.8%)</td>
<td>6 (11.5%)</td>
<td>3 (6.0%)</td>
<td>0.49</td>
</tr>
<tr>
<td>Bleeding</td>
<td>3 (2.9%)</td>
<td>1 (1.9%)</td>
<td>2 (4.0%)</td>
<td>0.61</td>
</tr>
<tr>
<td>Other</td>
<td>16 (15.7%)</td>
<td>9 (17.3%)</td>
<td>7 (14.0%)</td>
<td>0.79</td>
</tr>
<tr>
<td>Concomitant diseases</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>66 (64.7%)</td>
<td>27 (51.9%)</td>
<td>39 (78.0%)</td>
<td>0.01*</td>
</tr>
<tr>
<td>History of congestive heart failure</td>
<td>55 (53.9%)</td>
<td>21 (40.4%)</td>
<td>34 (69.4%)</td>
<td>0.005*</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>48 (47.1%)</td>
<td>23 (44.2%)</td>
<td>25 (50.0%)</td>
<td>0.69</td>
</tr>
<tr>
<td>Coronary heart disease</td>
<td>41 (40.2%)</td>
<td>13 (25.0%)</td>
<td>28 (56.0%)</td>
<td>0.002*</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>39 (38.2%)</td>
<td>15 (28.8%)</td>
<td>24 (48.0%)</td>
<td>0.07</td>
</tr>
<tr>
<td>Intermittent claudication</td>
<td>18 (17.6%)</td>
<td>9 (17.3%)</td>
<td>9 (18.0%)</td>
<td>1.0</td>
</tr>
<tr>
<td>End-stage renal disease</td>
<td>14 (13.9%)</td>
<td>5 (9.6%)</td>
<td>9 (18.4%)</td>
<td>0.26</td>
</tr>
<tr>
<td>History of stroke</td>
<td>8 (7.8%)</td>
<td>1 (1.9%)</td>
<td>7 (14.0%)</td>
<td>0.03*</td>
</tr>
</tbody>
</table>

The table provides data (mean±SD) of the overall study population and the subgroups with sinus rhythm and atrial fibrillation. Testing for significant differences between the subgroups were performed using unpaired 2-tailed $t$ tests for numeric data and $\chi^2$ test (Fisher exact test) for categorical data.

* $P<0.05$ was considered significant.

### Table 2. Accuracy of Blood Pressure Measurement Devices in Patients With Sinus Rhythm (n=52) and Atrial Fibrillation (n=50)

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Upper Arm Oscillometric Device (Omron M5)</th>
<th>Wrist Oscillometric Device (Omron R5)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SR</td>
<td>AF</td>
</tr>
<tr>
<td>SBP, mmHg</td>
<td>128.2±18.6</td>
<td>121.5±17.3</td>
</tr>
<tr>
<td>DBP, mmHg</td>
<td>69.7±10.1</td>
<td>68.1±9.6</td>
</tr>
<tr>
<td>Bias of SBP, mmHg</td>
<td>−3.9±10.4</td>
<td>−7.4±11.3</td>
</tr>
<tr>
<td>Bias of DBP, mmHg</td>
<td>8.6±9.8</td>
<td>8.3±8.1</td>
</tr>
<tr>
<td>Intraindividual variability of SBP, mmHg</td>
<td>3.3±2.0</td>
<td>5.7±5.2</td>
</tr>
<tr>
<td>Intraindividual variability of DBP, mmHg</td>
<td>2.1±1.4</td>
<td>3.5±3.1</td>
</tr>
</tbody>
</table>

Data on systolic blood pressure (SBP) and diastolic blood pressure (DBP) constitute the mean of 3 consecutive measurements (mean±SD). Readings 1 to 3 refer to invasive measurements performed before each one of the 3 measurements with the Omron M5, and readings 4 to 6 refer to the invasive measurements before the Omron R5 device. The bias of SBP and DBP to invasively assessed values and the with-in-subject variability were calculated. Groups were compared by unpaired 2-tailed $t$ tests.

AF indicates atrial fibrillation; and SR, sinus rhythm.

* $P<0.05$ was considered significant.
Discussion
To date, all reports on the impact of AF on the accuracy of oscillometric blood pressure monitoring have used auscultatory sphygmomanometry as reference method. Sphygmomanometry, however, may be biased by AF as well. Therefore, the AHA recommended using intra-arterial blood pressure measurement as reference technique. The present work has put this recommendation into practice. AF slightly but significantly increased the intraindividual variability of oscillometric measurements. This increased intraindividual variability did not significantly impair, however, the accuracy of the oscillometric monitors after 3 consecutive measurements. Because the coincidence of AF and arterial hypertension is high, these findings may be of major clinical interest.

The prevalence of both entities increases with age with AF reaching ≈10% in subjects ≥80 years and hypertension >60%
in those >60 years of age. Moreover, there is a causal relation between these diseases: hypertensive heart disease is the most common underlying disorder in patients with AF. Both AF and hypertension are risk factors for thromboembolic stroke. Therefore, blood pressure control is of outstanding importance in patients with AF. Blood pressure self-measurement, today almost exclusively performed by oscillometric devices, is a better predictor of cardiovascular events than office blood pressure. Moreover, home blood pressure monitoring improves both therapeutic compliance and blood pressure control. Especially for older patients, oscillometric blood pressure monitors provide several advantages: the measurement procedure is easier than auscultatory sphygmomanometry. Sphygmomanometry requires an accurate detection of the Korotkoff sounds, which may be impaired by hearing-loss in older patients. Moreover, oscillometry does not require a transducer to be placed over the brachial artery. Thus, exact placement of the cuff is less critical. Our findings are in accordance with previous reports that compared oscillometric blood pressure with auscultatory sphygmomanometric values. The authors concluded that validated oscillometric automated blood pressure monitors may be used in patients with AF.

How can it be explained that AF increased the within-subject variability of oscillometric measurements without affecting accuracy in the Bland–Altman analysis? First, the increase in variability was rather modest (≤2.5 mm Hg). Second, the present study design involved 3 measurements for each device. Obviously, this repetition of measurements was enough to counterbalance the higher variability of oscillometry in AF. The mean bias after 3 measurements did not significantly differ in subjects with AF and sinus rhythm. Interestingly, there is already a recommendation by American and European guidelines to perform repeated blood pressure measurements using auscultatory sphygmomanometry in patients with AF to overcome the variations of stroke volume. As for the present findings, this recommendation may be transferred to oscillometric measurements as well.

However, our data show that, independent of AF, the oscillometric devices underestimate systolic blood pressure, although the devices passed clinical validation procedures. The main problem with oscillometry is that the amplitude of the oscillations depends on several factors other than blood pressure, most importantly the elasticity of the arteries. Advanced atherosclerosis results in high arterial stiffness and hence poor oscillation transmission. Therefore, in older people with stiff arteries and high pulse pressure, the mean arterial pressure may be underestimated. This phenomenon is evident in our study as well. The mean age of our study population was 68 years and, independent of AF, systolic blood pressure was significantly underestimated by both oscillometric devices. The extent of underestimation was the highest in the wrist device (7.8 mm Hg). We have previously shown that the accuracy of wrist blood pressure monitors crucially depends on the extent of pulse pressure as a measure of arterial stiffness. It has to be kept in mind that validation procedures require a covering of different ranges of blood pressure but not different ranges of age. The present findings are a further argument that future validation protocols should take this phenomenon into account and should, therefore, require the inclusion of older subjects as well. A slight underestimation of systolic blood pressure and overestimation of diastolic blood pressure is a well-described phenomenon in sphygmomanometry as well.

What is the consequence of the present study for daily clinical practice? AF did not significantly impair the accuracy of oscillometric blood pressure measurement, if repeated measurements were performed. As described above, previous reports using sphygmomanometry as reference method have shown that oscillometric devices perform satisfactorily in AF. Now, by using invasively assessed intra-arterial pressure as reference, we confirmed these findings. Therefore, we believe that there is no more robust reason to advise patients with AF against using validated oscillometric devices, if they are unable to perform sphygmomanometric self-measurements because of hearing-loss or cognitive and manual disabilities. However, patients have to be instructed to perform 3 measurements to compensate for the higher intraindividual variability.

The study is limited by the fact that recruitment took place in an intensive or intermediate care setting. Thus, there is a selection bias toward a higher level of comorbidity. However, this potential selection bias affected both the group of AF and the group of sinus rhythm. Moreover, measurements were performed only in those patients who had proven hemodynamic and respiratory stability, ideally right before removal of the arterial catheter and transfer to a peripheral ward. Use of vasopressors and mechanical ventilation were exclusion criteria. It has to be kept in mind that the benefit of strict blood pressure control is higher in patients with a high cardiovascular risk than in healthy subjects. A blood pressure monitor that provides exact results in healthy subjects but has a low validity in patients with relevant comorbidities is of limited clinical benefit. Finally, the study should be repeated using oscillometric devices from other manufacturers because the software tools for the handling of arrhythmia might differ.

Perspectives

The present findings indicate that AF leads to a higher intra-individual variability of oscillometric blood pressure values. However, AF does not significantly attenuate the accuracy of oscillometry after 3 consecutive measurements. Thus, the JNC7 and ESH recommendation to perform several measurements using sphygmomanometry in AF may apply to oscillometry as well. Patients with AF are at extraordinary risk for cardiovascular events and benefit from strict blood pressure control in a particular manner. As for the present findings, we believe that AF should be no reason for generally depriving patients of blood pressure home monitoring by oscillometric devices.

Disclosures

None.

References


Novelty and Significance

What Is New?

- The present work evaluates the accuracy of oscillometry in atrial fibrillation using intra-arterial blood pressure as reference for the first time.
- The within-subject variability of the oscillometric measurements was higher in patients with atrial fibrillation compared with sinus rhythm.
- The biases of systolic and diastolic blood pressure did not differ in the presence or absence of atrial fibrillation after 3 consecutive measurements.

What Is Relevant?

- Many elderly subjects with atrial fibrillation are unable to perform sphygmomanometric self-measurements. For these patients, automated oscillometric devices are a suitable alternative, if repeated measurements are performed.

Summary

If oscillometric automated blood pressure measurement devices are used in atrial fibrillation, repeated measurements should be performed to overcome the increased intra-individual variability.
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_Hypertension_. 2013;62:579-584; originally published online July 29, 2013;
doi: 10.1161/HYPERTENSIONAHA.113.01426

_Hypertension_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2013 American Heart Association, Inc. All rights reserved.
Print ISSN: 0194-911X. Online ISSN: 1524-4563

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