ORIGINAL RESEARCH

Comparison of two oscillometric blood pressure monitors in subjects with atrial fibrillation

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Abstract

Objective: To compare blood pressure readings obtained with two commonly used oscillometric monitors: Omron HEM 711 AC (OM) and Welch-Allyn 52000 series NIBP/oximeter (WA) with mercury sphygmomanometers (Merc) in subjects with atrial fibrillation.

Methods: We recruited 51 hemodynamically stable subjects with atrial fibrillation. Fifty four subjects in normal sinus rhythm served as controls. Supine blood pressure readings in each arm were recorded simultaneously using one monitor and Merc. The second monitor then replaced the first and readings were repeated. Merc was then switched to the opposite arm, and both monitors retested. Apical heart rates were ascertained with a stethoscope. We used the averaged, same arm Merc readings as “gold standard”.

Results: Automated blood pressure readings were obtained in all control subjects and in all but three of those with atrial fibrillation. Both monitors, and operators, noted a difference between apical and radial/brachial pulse rates: apical-recorded: Merc 6.1 ± 15.0 ; OM 5.5 ± 13.7 ; WA 10.0 ± 21.2 beats per minute. Both monitors were accurate in controls: over 90% of readings were within 10 mmHg of averaged Merc, and both achieved European Hypertension Society standards. In subjects with atrial fibrillation, about one quarter of all oscillometric readings differed from Merc by more than 10 mmHg. Both falsely high and falsely low readings occurred, some up to 30 mmHg. There was no relation between accuracy and heart rate.

Conclusions: Single blood pressure readings, taken with oscillometric monitors in subjects with atrial fibrillation

differ, often markedly, from those taken manually. Health care professionals should record multiple readings manually, using validated instruments when making therapeutic decisions.

Atrial fibrillation is the most common chronic arrhythmia; occurring in up to 9% of people aged 65 or more¹. It increases the risk of stroke and death by at least 1.5 fold. Atrial fibrillation is present in up to 17% of hypertensives.² Hypertension has been implicated as a causative factor in 14% of cases of atrial fibrillation.

Accurate blood pressure recording in subjects with atrial fibrillation is problematic. Not only does the blood pressure itself vary over time, but Karotkoff sounds may vary in pitch and amplitude, and some may be well outside the “average” systolic or diastolic pressure. Guidelines recognize this problem but are generally silent on the proper way to record such readings.³ Some recommend recording the average of multiple, auscultatory readings,^{4,5,6} while other make no specific recommendation.⁷

Oscillometric blood pressure monitors have become increasingly common both in hospitals and in physicians offices.⁸ To our knowledge, none have

been validated via recognized protocols in subjects with atrial fibrillation. Furthermore, often a single blood pressure reading is recorded, and may lead to therapeutic decisions. If there was a large error in such a single reading, inappropriate treatment could result.

We recently encountered a patient with longstanding hypertension and atrial fibrillation, dyspnea on exertion, left ventricular hypertrophy and marked diastolic dysfunction. His home monitor readings averaged less than 130/80, but showed considerable variation (116/74 to 210/90). Our averaged clinic readings were 165/84, leading us to intensify his regimen.⁹ Ordinarily, we place considerable weight on accurate home readings. We therefore decided to test the accuracy of automated monitors.

Specifically, we compared blood pressure readings obtained with a mercury sphygmomanometer with those of two commonly used oscillometric monitors, in subjects with and without atrial fibrillation. We chose the Omron HEM 711 AC which is commonly used in the home, and the Welch-Allyn 52000/NIBP, which is used in our hospital.

Methods

Subjects

Our subjects were men or women, 18 years or older, either outpatients or those hospitalized at Royal University Hospital, with stable heart rate and blood pressure for 24 hours. We excluded inpatients whose recorded heart rate or blood pressure varied by more than 50%, who had had surgery within 24 hours, or had other severe illness. Outpatients were asymptomatic and attending the Cardiovascular Risk Factor Reduction Clinic.¹⁰

Patients with atrial fibrillation were identified by routine electrocardiography or telemetry, and confirmed clinically, at the time of measurement. Control subjects were in sinus rhythm on clinical examination and had no history of atrial fibrillation. We excluded those with more than 2 extrasystoles per minute.

All subjects gave informed consent and the protocol was approved by the University of Saskatchewan Biomedical Ethics Committee (EC 2006-229).

We used the Omron HEM 711AC home monitor, which, according to the manufacturer has met criteria established by the European Hypertension Society, the British Hypertension Society and the Association for the Advancement of Medical Instrumentation {http://www.healthcare.omron.co.jp/english/vali_us.php} and the Welch-Allyn 52000 series NIBP/oximeter, a commonly used model in our hospital. Both are self-inflating digital, oscillometric monitors. Our comparator was a standard mercury sphygmomanometer (Py-Mah Trimline, Trimline Medical Products, Branchburg, NJ).

Protocol

We collected demographic and anthropomorphic data for each subject.

Persons recording manual blood pressure had completed our locally developed "Blood Pressure Measurement course".¹¹ They measured apical heart rate via auscultation.

Because there was no published, validated blood pressure measurement protocol for patients with atrial fibrillation, we designed the following. All measurements were taken in the supine position, the patients had voided, had not smoked, eaten or consumed caffeinated beverages for 30 minutes, and had rested 5 minutes. Cuff size was determined by arm circumference according to the manufacturers. Two operators obtained readings on each patient. We used the supine position to ensure that both arms were supported and that both operators had room to record their readings.

A mercury sphygmomanometer cuff was applied to one arm and one of the automated monitors (in random order) on the other. Blood pressure was recorded simultaneously, with the manual operator using Canadian Hypertension Education Program technique (other than the seated position).⁵ Then, the other

TABLE 1. Subject characteristics

	AFib (n=51)	Cntrl (n=54)	p*
Sex (m/f)	30/21	35/19	0.55
Age	73.8 (12.4)	58.3 (12.7)	0.85
Apical HR	82.9 (15.5)	70.4 (13.4)	0.303
SBP	124.0 (22.9)	129.1 (17.3)	0.046
DBP	68.7 (10.1)	77.0 (11.7)	0.736

AFib: atrial fibrillation; Cntrl: subjects in normal sinus rhythm; m/f: male, female; HR: heart rate; SBD, DBP: systolic and diastolic blood pressure (mean of 4 mercury sphygmomanometry readings); figures in parentheses are standard deviation.

* calculated with Fishers exact test for age, one way ANOVA for others

automated monitor was substituted for the first one, and the procedure repeated.

Finally, the mercury sphygmomanometer cuff was transferred to the other arm, and the two automated monitors tested in similar fashion. Thus we had 8 blood pressure and heart rate recordings for each subject: 2 on each arm with the mercury sphygmomanometer, and one on each arm with each of the automated monitors.

For subjects with atrial fibrillation, we asked observers to record systolic blood pressure when “most beats were heard” and diastolic blood pressure when “most beats disappeared”.

We included the group of patients in sinus rhythm in order to test the validity of the protocol.

Statistical analyses

We used the average of the two mercury readings on an arm as our “gold standard” and compared each manometer’s reading on that arm.

We set “clinically reasonable accuracy” to demonstrate that 90 percent of the automated readings would fall within 15 mmHg of our gold standard¹². Assuming that the average systolic blood pressure was 130 mmHg in each group we required 39 “arms”. However, because of the uncertainty of these assumptions we planned to enroll 50 subjects (100 arms) in each group.

TABLE 2. Heart rates and pulse deficits

	Apex-pulse	Apex-OM	Apex-WA
AFib	6.1 (15.0)	5.5 (13.7)	10.0 (21.2)
Cntrl	0.7 (5.4)	0.3 (5.4)	0.1 (4.7)

Figures in parentheses are standard deviation. OM: Omron HEM 711 AC; WA: Welsh-Allyn 52000 series NIBP/oximeter. Other abbreviations same as Table 1.

Standard descriptive statistics and linear regression were performed using StatMost 3.2 for Windows (Datamost Corp, Sandy, UT)

Results

Subject characteristics are shown in Table 1. There were more men than women in each group. Subjects with atrial fibrillation were numerically older and had lower systolic and diastolic pressures. For systolic blood pressure the difference was statistically significant.

Adequate readings with both automated monitors were obtained on all control subjects, but not on all subjects with atrial fibrillation. In two of the latter group (4%) we could not obtain a reading with either monitor, while we failed to obtain readings with one of the two in two other subjects.

Accuracy of heart rate recording is shown in Table 2. In general all methods underestimated the apex rate (the “pulse deficit”) in subjects with atrial fibrillation, but were quite precise in control subjects.

Figures 1 and 2 are Bland-Altman type plots for systolic and diastolic readings with each monitor, compared to those taken with the mercury sphygmomanometer, for each group. There appears to be greater deviation from mercury readings with both monitors in subjects with atrial fibrillation.

Table 3 shows the proportion of readings within defined ranges from the averaged mercury readings for subjects with sinus rhythm. Both devices would likely be rated “pass”; the small deviation at ≤ 5 mmHg for the Welsh-Allyn monitor (57% observed vs. $\geq 60\%$ expected) would not likely be clinically significant. Indeed it was explained by 2 subjects

FIGURE 1. Bland-Altman Type Plots for Systolic Blood Pressure (SBP).

AFib: subjects in atrial fibrillation; NSR: subjects in normal sinus rhythm; OM: Omron HEM 711 AC monitor; WA: Welsh-Allyn 52000 series NIBP/oximeter monitor. Values are mmHg.

TABLE 3. Percent of oscillometric readings within 5, 10 or 15 mmHg of averaged mercury readings in control subjects (n=108 arms).

	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
ESH standard ¹²	60	75	90
OM			
SBP	65	89	96
DBP	65	91	100
WA			
SBP	57	90	95
DBP	70	98	99

ESH: European Hypertension Society. Other abbreviations same as Table 2.

TABLE 4. Percent of oscillometric readings within 5, 10 or 15 mmHg of averaged mercury readings in subjects with atrial fibrillation (n=96 arms).

	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
ESH standard ¹²	60	75	90
Omron			
SBP	49	72	84
DBP	47	77	92
WA			
SBP	46	72	81
DBP	57	86	96

Abbreviations same as Table 3.

FIGURE 2. Bland-Altman Type Plots for Diastolic Blood Pressure (DBP). Abbreviations same as Figure 1.

whose readings were 6 and 7 mmHg different than the average mercury reading. Table 4 shows similar data in subjects with atrial fibrillation. Both monitors would likely be rated “fail”. About one quarter of readings differed from mercury readings by more than 10 mmHg and 2 subjects showed a difference of over 30 mmHg systolic and 20 mmHg diastolic pressures with one or other of the monitors. The monitors appeared to achieve about the same level of accuracy.

When atrial fibrillation subjects were divided into those above and below the median heart rate, there was no difference in the accuracy of the readings (data not shown).

Figure 3 shows regression lines with 95% confidence intervals, for *simultaneous* readings in arms of subjects with atrial fibrillation. For the Omron monitor the regression coefficients for systolic and diastolic pressure were 0.835 and 0.739; for the Welsh-Allyn, 0.768 and 0.688.

Figure 4 shows similar regression lines for subjects in sinus rhythm. The correlation coefficients were, numerically greater: ranging from 0.848 to 0.9946.

FIGURE 3. Simultaneous readings on opposite arms for subjects in atrial fibrillation. Abbreviations same as Figure 1.

Discussion

These data show that blood pressure readings, obtained with oscillometric monitors, are likely to be similar to those taken manually in subjects in sinus rhythm, but not in those with atrial fibrillation. Indeed, only about 1 in 10 single oscillometric readings differed from averaged mercury readings by more than 10 mmHg in subjects in sinus rhythm, while 1 in 4 did so in subjects with atrial fibrillation. Both “falsely high” and “falsely low” readings were recorded so that the error appears to be random and unpredictable. We found no relation between the size of

the error and apical heart rate, absolute blood pressure or any other easily measurable clinical parameter.

A limitation of our study is the lack of a true “gold standard” for blood pressure measurements in subjects with atrial fibrillation. Experts recommend “several readings” in order to estimate the true blood pressure. We took the average of only two mercury readings from each arm. We feel that more readings would have caused discomfort for very little extra accuracy. Another limitation is our comparison of only one oscillometric reading with the average of the mercury readings. Perhaps more oscillometric readings would have approached the mean. However, in practice, de-

FIGURE 4. Simultaneous readings on opposite arms for subjects in normal sinus rhythm. Abbreviations same as Figure 1.

cisions are often made to change or withhold therapy on the basis of single readings. Our sinus rhythm group showed good agreement between the two methods using this protocol.

Oscillometric recorders use a “maximal amplitude” algorithm, in which the pressure at maximum oscillation of the arm is assumed to equal mean arterial pressure.¹³ Systolic and diastolic pressures are then calculated using proprietary algorithms. An irregular pulse may make it more difficult to ascertain the pressure at maximal oscillation, as the pulse pressure will change from beat to beat. Furthermore, the calculations for systolic and diastolic pressure assume

that the R-R interval is constant.¹⁴ It is not surprising therefore, that such monitors are different than mercury sphygmomanometry readings in subjects with atrial fibrillation.

Other attempts to assess the accuracy of oscillometric recorders in atrial fibrillation have used different protocols. Stewart and colleagues compared five monitors in 30 patients with atrial fibrillation, using a same-arm, sequential method with a mercury-based sphygmomanometer as gold standard.¹⁵ They found that one of the tested monitors using a microphone to detect Korotkoff sounds was within 5 mmHg of the mercury based monitor in about 70% of readings. All

other monitors were less accurate. They did not include subjects in normal sinus rhythm and none of the monitors had been validated with accepted protocols. Jani and colleagues compared four mercury readings with four oscillometric readings in the same arm in 20 subjects with atrial fibrillation and 20 in normal sinus rhythm.¹⁶ Although the variation among readings was greater in atrial fibrillation, all readings were within 15 mmHg. Given the small number of subjects, the possibility of a type 2 error exists. Finally, Anastas et al compared a Welch-Allyn Vital Signs monitor with an aneroid instrument in 53 subjects with atrial fibrillation.¹⁷ They found no significant difference in systolic blood pressure but a 3.3 mmHg difference in diastolic blood pressure. They did not use a comparison group in normal sinus rhythm.

Ambulatory monitors using oscillometry have been used in patients with atrial fibrillation. Blood pressure variability, as assessed by the standard deviation from the mean seems greater than in subjects in sinus rhythm.¹⁸ Whether the readings are as accurate in predicting complications of hypertension, as in patients in sinus rhythm is unknown.

Our protocol compared widely used regular monitors, includes a sinus rhythm control group and is adequately powered to detect significant differences. Neither monitor performed up to current standards. It may be argued that, had we taken more readings with the automated monitors, their accuracy would have approached that of mercury sphygmomanometry. Nevertheless, in clinical practice, therapeutic decisions will often be made on the basis of a single reading.

Advances in oscillometry will undoubtedly occur.¹⁹ However, for patients with irregular heart rhythms, it appears likely that multiple manual blood pressure recordings using standard Riva-Rocci technique will continue to be required.

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