Repeatability of Automated Ambulatory Blood Pressure Measurements

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Background. The repeatability of 24-hour automatic ambulatory blood pressure measurements recorded by noninvasive equipment (Del Mar Pressurometer IV) was assessed to determine the intrapatient variability of this test.

Methods. The usual antihypertensive medications of 73 patients with documented essential hypertension (supine diastolic blood pressure of 95 to 119 mm Hg) were withdrawn, and the patients were treated with placebo medication for 6 weeks. At the end of the placebo period, ambulatory blood pressure measurements of each patient were recorded every 15 minutes for 24 hours on two separate occasions 1 week apart.

Results. There was no significant difference in either the 24-hour systolic or diastolic blood pressure for the entire group between weeks. A mean difference for individual patients between the first and second recording within 5 mm Hg was observed in 49.3% and 52.1% of patients for 24-hour systolic and diastolic blood pressure, respectively. The correlation coefficient for 24-hour systolic blood pressure was greater than 24-hour diastolic blood pressure ($r = .87$ vs $r = .67$). A difference greater than 18.1/14.9 mm Hg for systolic/diastolic blood pressure would be required to assign a significant ($P < .05$) change in blood pressure between two recordings in the same patient.

Conclusions. These data quantify the usefulness of 24-hour ambulatory blood pressure measurements for a group of subjects. However, mean 24-hour ambulatory blood pressure varies significantly for individuals. Intrapatient variability may limit the usefulness of a single 24-hour ambulatory recording for an individual patient and suggests the need for more than one measurement to establish a level of blood pressure.

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Because the variability of routine office blood pressure measurements for individual patients is large, the diagnosis of hypertension should be made only after three readings on three different occasions. Indirect blood pressure measured one to several times on repeated visits to a clinic or office has been shown to fall from the initial to the last visit in a majority of patients.[1–3] This decline and at other times elevation[4] of office blood pressure are reasons for interest in the use of home and work blood pressure measurements and indirect automated ambulatory blood pressure monitoring.[5,6] Automated ambulatory blood pressure measurements may decrease the number of office visits required to establish a diagnosis of hypertension before initiation of an active antihypertensive regimen. Intra-arterial automated ambulatory blood pressure measurements, in contrast to office blood pressure measurements, do not fall with placebo, are reproducible,[4–6] and vary in a circadian pattern.[7,8] Repeated intra-arterial ambulatory blood pressure monitoring is not practical, however, for evaluating large groups of patients.

The circadian pattern of readings from ambulatory blood pressure monitoring, and other episodic variations in blood pressure, make a 24-hour blood pressure average derived from collected measurements at 7.5- to 15-minute intervals attractive. These averages exclude outlier measurements according to conservative rules. The placebo phase of a large clinical research study provided an opportunity to assess the repeatability of the 24-hour mean blood pressure measurement by noninvasive automatic ambulatory blood pressure monitoring determined twice, 1 week apart. With the information given in this study, the user of 24-hour averages could estimate the group variability, as well as individual variability that could occur from day to day. The study also provided an

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opportunity to determine whether there was a reduction of the group mean 24-hour average between the first and second measure. Furthermore, it allowed us to compare findings in a group of 73 subjects with those in several smaller studies.[9–15] The questions asked in our analyses were: (1) Is ambulatory blood pressure repeatable for groups of patients? and (2) Is ambulatory blood pressure repeatable for the individual patient?

Methods

Study Population

Seventy-three patients with essential hypertension (as determined by history, physical examination, and routine screening laboratory data) with supine diastolic office blood pressure on placebo of 95 to 119 mm Hg were studied. The mean age was 46.9 ± 12.1 years. Forty-six patients (63%) were white, 25 (34%) were black, one was Asian, and the race of one patient was not recorded. Women accounted for 61.6% of the study population. Women were allowed to participate if they were sterile or practicing a medically supervised method of contraception and were not pregnant at the time of enrollment. Patients with a mean supine diastolic blood pressure outside the range of 95 to 119 mm Hg, secondary or accelerating hypertension, cardiac arrhythmias, recent myocardial infarction, or significant renal or hepatic disease were excluded from the study population. Patients for whom ambulatory blood pressure could not be calibrated or repeated were excluded. All participants gave written informed consent. This protocol was approved by the investigational review committee of the Medical College of Georgia.

Study Design

Data were collected during the placebo phase of a prospective, randomized, double-blind, placebo-controlled parallel-groups study. All cardiovascular, bronchodilator, and psychotropic medications were discontinued on entry into a 6-week placebo phase. Two blood pressure readings were taken 2 to 5 minutes apart by a trained observer, using an appropriate size cuff on the same arm, at weekly intervals, at generally the same time of the day, according to the standard of the American Heart Association.[16] No smoking was permitted 30 minutes before office blood pressure measurement.

To qualify for enrollment, patients were required to demonstrate an average supine diastolic blood pressure 95 to 119 mm Hg recorded manually by a standard mercury manometer at two consecutive visits during the qualifying phase. Ambulatory blood pressure measurements were initially calibrated by a Y-tube connection to a mercury manometer. Only if the manual measurements were within 5 mm Hg of the ambulatory recorder was a 24-hour recording obtained. Ambulatory blood pressure monitoring was performed during the last two placebo visits at 7-day intervals. Ambulatory blood pressure monitoring was repeated according to the daily conditions (work status) of the original recording.

Ambulatory Blood Pressure

Ambulatory blood pressure recording was performed with a Del Mar Avionics Pressurometer IV recorder (Del Mar Avionics, Irvine, Calif), which was gated to the R wave of the electrocardiogram. The sampling interval was every 15 minutes over a period of approximately 24 hours. Although there are no standard criteria, these recorded data were edited according to criteria to exclude measurements that measured systolic blood pressure less than 50 mm Hg or greater than 260 mm Hg, diastolic blood pressure less than 30 mm Hg or greater than 150 mm Hg, pulse pressure less than 20 mm Hg or greater than 110 mm Hg, and heart rate less than 40 beats per minute or greater than 140 beats per minute. Manual deletions of data were not performed in addition to the automated deletions during editing. The mean systolic blood pressure and diastolic blood pressure were calculated for the 24-hour period. The total recording interval was also recorded. *Blood pressure load,* the percentage throughout the day of systolic readings greater than 140 mm Hg or diastolic readings greater than 90 mm Hg, was calculated for the 24-hour period for each recording.

Statistical Analysis

Results for analysis were the 24-hour average for each of 73 subjects for two visits. The data were analyzed according to a one-way analysis of variance with repeated observations of the patients. This provided an estimate of the variability within patients, an estimate of patient-to-patient variability, and a test of whether there was a significant difference between the mean blood pressure on the first and second visit.[17,18]

To aid readers in relating the results of this study to others in the literature,[9–15] product-moment correlation coefficients were also computed for pairs of average blood pressures, although these statistics do not provide an assessment of changes in mean blood pressure from the two occasions.

As a check on the assumption of homogeneous variance within subjects, the difference of the 24-hour

Table 1. One-Factor ANOVA Repeated Measures: Systolic Blood Pressure

Source	*df*	Sum of Squares	Mean Square	*F* Test	*P* Value
Between subjects	72	41760.2	580	14.3	<.001
Within subjects	73	2952.9	40.5*		
Weeks	1	4.5	4.5	.11	.742
Residual	72	2948.4	40.95		
Total	145	44713.1			

**The standard deviation for a subject is* $\sqrt{\text{mean square (within subjects)}}$. *To calculate how much change from one 24-hour average blood pressure to another 24-hour average blood pressure would be needed for a significant difference in average blood pressure at two standard deviations* for an individual subject, *multiply the standard deviation (as calculated in the previous sentence)* $\times 2 \times \sqrt{2}$. *This would be 18.1 mm Hg for systolic blood pressure and 14.9 mm Hg for diastolic blood pressure.*
ANOVA denotes analysis of variance.

Table 2. One-Factor ANOVA Repeated Measures: Diastolic Blood Pressure

Source	*df*	Sum of Squares	Mean Square	*F* Test	*P* Value
Between subjects	72	10241.9	142.2	5.2	<.001
Within subjects	73	1999.5	27.4*		
Weeks	1	6.0	6.0	.2	.644
Residual	72	1993.6	27.7		
Total	145	12241.4			

**The standard deviation for a subject is* $\sqrt{\text{mean square (within subjects)}}$. *To calculate how much change from one 24-hour average blood pressure to another 24-hour average blood pressure would be needed for a significant difference in average blood pressure at two standard deviations* for an individual subject, *multiply the standard deviation (as calculated in the previous sentence)* $\times 2 \times \sqrt{2}$. *This would be 18.1 mm Hg for systolic blood pressure and 14.9 mm Hg for diastolic blood pressure.*
ANOVA denotes analysis of variance.

blood pressure (set 1 − set 2) was plotted against the mean of the two sets of 24-hour blood pressure readings for each patient. This form of plotting clearly demonstrates whether the variation from each of the 2 weeks changes with the mean levels of blood pressure.[17] This did not show that the variation was dependent on the level of hypertension.

Results

There were two 24-hour ambulatory blood pressure recordings for each of the 73 hypertensive subjects. For a complete 24-hour period, a patient would have 96 readings. The average number of measurements per patient after editing was 89.2 in the first set and 86.3 in the second set. Over 90% of the total number of readings exceeded 75 in set 1 and 68 in set 2.

The mean ± standard deviation of the 24-hour systolic/diastolic blood pressure readings were, for set 1, 147.0 ± 17.6/92.9 ± 9.4 mm Hg; and, for set 2, 147.4 ± 17.6/93.4 ± 9.0 mm Hg. These averages should be interpreted with the understanding that normal values recorded by ambulatory blood pressure monitoring are lower than the values obtained with a mercury column.[19] The mean difference ± standard deviation between each set of the 73 24-hour systolic and diastolic blood pressures was −0.35 ± 9.1 and −0.40 ± 7.4 mm Hg. If the mean differences were calculated without respect to the direction of the difference, then the mean difference ± standard deviation would be 6.7 ± 6.0 mm Hg for systolic and 5.6 ± 4.8 mm Hg for diastolic 24-hour ambulatory blood pressures. The correlation coefficient between the two 24-hour measurements for systolic blood pressure was .87 and for diastolic blood pressure, .67.

Results of the repeated measures analysis of variance given in Tables 1 and 2 show that neither mean systolic blood pressure (P = .742) nor mean diastolic blood pressure (P = .644) varied significantly from the first week to the second. As expected, there is significant variability among individual patients (F test = 14.3/5.2, $P < .001$ for both systolic and diastolic blood pressures). The standard deviations of blood pressure for a particular patient for systolic blood pressure and diastolic blood pressure were 6.4 and 5.2 mm Hg, respectively. These estimates are derived from the square root of the residual mean square in Table 1. Because of the observed level of variability, a difference of 18.1/14.9 mm Hg for systolic/diastolic blood pressure would be required to indicate a statistically significant change ($P < .05$) between two readings on the individual patient.

Figure 1 shows a frequency histogram of the mean difference of set 1 (placebo 1) and set 2 (placebo 2) for 24-hour systolic blood pressure and diastolic blood pressure. For the systolic blood pressure, the mean difference was within 5 mm Hg in 49.3% of the patients and within 10 mm Hg in 78.1% of the patients. For the diastolic blood pressure, the mean difference was within 5 mm Hg in 52.1% of the patients and within 10 mm Hg in 80.8% of the patients.

Blood pressure load has been reported to be useful

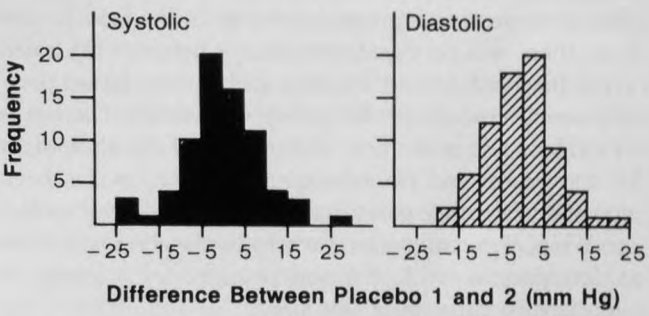

Figure 1. Frequency histogram of difference between set 1 and set 2 (placebo 1 and placebo 2) mean 24-hour systolic and diastolic blood pressures of 73 hypertensive patients.

Table 3. Studies Evaluating Reproducibility of Noninvasive Blood Pressure Monitors

Investigator	Monitor	Population (No.)	Interval
Berglund et al[11]	Del Mar Pressurometer III	Hypertensives (9)	8 wk
Conway et al[14]	COPAL UA 231	Hypertensives (42)	1 mo
des Combes et al[12]	Remler M2000	Normotensives (84)	3–4 mo
Drayer and Weber[10]	Del Mar Pressurometer III	Normotensives (56)	2–8 wk
Fitzgerald et al[15]	Remler M2000	Hypertensives (19)	2–6 wk
James et al[9]	Spacelabs ICR 5200	Normotensives (14)	2 wk
		Hypertensives (13)	
Vaisse et al[13]	Spacelabs	Normotensives (10)	30 d
		Normotensives (15)	15 d
The present study	Del Mar Pressurometer IV	Hypertensives (73)	1 wk

for diagnosing hypertension.[20] The percent of systolic blood pressure readings exceeding 140 mm Hg (ie, systolic load) in set 1 was 58.3%, and in set 2, 58.5%. The percent of diastolic blood pressure readings exceeding 90 mm Hg (ie, diastolic load) for set 1 and set 2 was 56.3% and 56.8%, respectively. When one considers individual patients rather than the entire group, however, 39.7% of the patients had readings that were within 10%, and 15.1% had readings that were within 5% for diastolic load; 52.1% of the patients had readings that were within 10%, and 38.4% had readings that were within 5% for systolic load on repeat measurements.

Discussion

Population ambulatory blood pressure measurements are generally repeatable and follow a normal distribution. This property is useful in interpreting changes from one occasion to another, as would be the case in assessing the efficacy of treatment programs for an individual. In this study there was no significant change between the mean of the first and second 24-hour ambulatory blood pressure measurements for this group of patients. There was no artificial rise in the first 24-hour use of the equipment for the group and no subsequent decline, as has been reported with office measurements.[6] One 24-hour ambulatory blood pressure after 4 weeks of placebo is sufficient to determine a level of blood pressure for a group of hypertensive subjects of this size.

The mean difference ± standard deviation between two ambulatory blood pressure recordings was 6.7 ± 6.0 mm Hg and 5.6 ± 4.8 mm Hg for 24-hour average systolic and diastolic blood pressures, respectively. Based on our study, a difference of 18.1/14.9 mm Hg for systolic/diastolic blood pressure would be required to indicate a significant change ($P < .05$) between the two readings for the individual patient. This observation of intrapatient variability suggests that categorizing an individual based on ambulatory blood pressure readings as being either a "true" hypertensive or a "white coat" hypertensive might not be as straightforward as it appears.[21,22] Therefore, this may limit the usefulness of ambulatory monitoring for an individual patient based on a single 24-hour average, suggesting that more than one recording may be necessary to establish a level of blood pressure for a decision regarding therapy. This must be interpreted, however, in relation to an even greater individual variability between visits for office measurements.[23]

Comparison with Other Studies

Our data demonstrated a lower group test-retest correlation for 24-hour systolic blood pressure (.87 vs .93) and diastolic blood pressure (.67 vs .87) than James et al.[9] However, James et al (Table 3) used only 48 exactly matched hour-for-hour blood pressures over a 15-hour (±4 hours) interval rather than the entire 24-hour interval. Our study results for 24-hour diastolic blood pressure agree with Berglund et al[11] for test-retest correlation (.67 vs .64). Using the semiautomatic Remler M2000 recorder, des Combes[12] measured a lower correlation for systolic blood pressure ($r = .82$, n = 84) and a higher correlation for diastolic blood pressure ($r = .78$); how-

ever, this study was not exactly comparable to ours because the subjects actuated the device at 30-minute intervals for only 12 hours. This study of hypertensive subjects documented a close agreement of mean 24-hour systolic blood pressure within 10 mm Hg (78% vs 82%) but lower mean 24-hour diastolic blood pressure within 5 mm Hg (52% vs 73%) when compared with Drayer and Weber's study of 56 normotensive subjects.[10] It is possible that the variability of normotensive subjects is less than that of hypertensive subjects. Conway et al[14] reported a mean difference between two ambulatory blood pressure readings of 1.9/−0.33 mm Hg with a standard deviation of 8.1/5.6 mm Hg, which is similar to our findings of −0.35 ± 9.1/−0.40 ± 7.4 mm Hg. Finally, there was no significant decrease in average 24-hour blood pressure for the group for two noninvasive 24-hour ambulatory blood pressure measurements, which supports the findings reported in other studies.[9,10,12–15]

The correlations above have been reported for comparison purposes only; it should be noted that statisticians believe that a correlation coefficient is not the best method to assess the reproducibility of a test.[18,19] In fact, since the test measures the same variable (ie, blood pressure), it would be surprising if there were no correlation. Therefore, neither the correlation coefficient nor regression analysis may be appropriate. The Bland-Altman method[17] (plotting the difference of the 24-hour blood pressures [set 1 − set 2] against the mean of the two 24-hour blood pressures [(set 1 + set 2) ÷ 2] for each patient) is considered the best approach to assess the repeatability of a test. Assuming that the variance of differences does not change with increasing blood pressure levels, mean population changes from one ambulatory blood pressure measure to another (set 1 vs set 2) is done with either a paired *t* test or analysis of variance.

Blood pressure load, the percentage throughout the day of systolic readings greater than 140 mm Hg or diastolic readings greater than 90 mm Hg, may be useful for interpreting ambulatory blood pressure recordings.[20] Our results are similar to those of Zachariah et al[20] in established hypertensive subjects for systolic load (58% vs 48%) and for diastolic load (56% vs 59%). However, for diastolic load, 39.7% of the patients were within 10%, and 15.1% of the patients were within 5%; whereas, for systolic load, 52.1% of the patients were within 10%, and 38.4% of the patients were within 5% on repeat measurement. Whether this measurement represents an improvement over mean 24-hour blood pressure measurement in terms of repeatability for an individual patient cannot be determined by this study.

Sources of Variability

This study did not address the repeatability of office measurements compared with ambulatory measurements for individuals, although we have documented even greater variability in office measurements.[23] It has been previously demonstrated[24] that a single 24-hour ambulatory systolic or diastolic blood pressure correlates better with echocardiographic left ventricular wall thickness than either a single visit office measurement or multiple visit office measurements for a group of hypertensive patients (although the confidence limits were wide for individuals). Therefore, it might be assumed that ambulatory blood pressure measurements are more repeatable than office measurements because of the better correlation with target organ damage. Despite the risks associated with office blood pressure described in large epidemiological studies,[25] careful early studies have shown that the individual variability on a single occasion or between multiple occasions is very large.[26] Thus, future studies should compare the repeatability for individuals of office mercury manometer measurements with noninvasive automated ambulatory blood pressure measurements.

One possible explanation for the variability in repeated 24-hour blood pressure means for individual patients includes differences in daily activity. Although patients were restudied according to the daily conditions (work status) of the original recording, it is very difficult to control work effort, which has a strong impact on blood pressure values.[27] The true test of repeatability would be to study patients under completely controlled environmental conditions (which is impractical), so that the true intrinsic properties of blood pressure, rather than differing responses to variations in activity, can be tested for reproducibility. Even this approach would not control for psychological stressors that may have a pressor effect. Other sources of variability (in addition to dynamic and isometric exercise and emotion) include posture, sexual activity, micturation, defecation, ingestion of food and drink, smoking, caffeine, alcohol, and talking.[28]

It is also possible that the individual variability is due to the instrument used. Ambulatory blood pressure throughout the entire study was measured with several Del Mar Avionics Pressurometer IV recorders, an R wave–gated auscultatory device. No attempt was made to ensure that each patient was fitted with exactly the same monitor. Perhaps this instrument is less accurate than other devices that use the auscultatory method (Korotkoff sounds detected by piezoelectric device) or devices that use an oscillometric method (brachial artery oscillations transmitted to the cuff). Although there are mini-

mal standards (which are undergoing revision currently) in the United States for this equipment,[29] the validation studies for each piece of equipment may not be comparable, interdevice variability assessment is not required, and the required statistical methods have been questioned.[30] Therefore, one cannot exclude instrument artifact as the source of individual variability.

Summary

In summary, there was no significant difference between the mean of the first and second 24-hour ambulatory blood pressure measurements for a group of 73 patients after discontinuation of medications for 1 month. Because of the high rate of intrapatient variability, however, a difference greater than 18.1/14.9 mm Hg for systolic/diastolic blood pressures would be required to demonstrate a significant ($P < .05$) change between two 24-hour recordings for an individual patient. This implies a limited usefulness of ambulatory monitoring for an individual patient based on a single 24-hour average, and suggests that more than one reading may be necessary to establish a level of blood pressure. More studies are needed to compare the repeatability of office mercury manometer measurements with noninvasive automated ambulatory blood pressure measurements.

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