Skip Patterns in DINAMAP-Measured Blood Pressure in 3 Epidemiological Studies

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Abstract—Blood pressure measured by the oscillometric, automated device DINAMAP in 3 large population-based studies sponsored by the National Heart, Lung, and Blood Institute (The Atherosclerosis Risk in Communities Study, The Family Heart Study, and the Hypertension Genetic Epidemiology Network Study) were reviewed to determine an apparent skip pattern in the measurement values. Across the 3 studies, 2 different DINAMAP models were evaluated on >350 000 different blood pressure measurements. Measurements were taken in various positions, on both arm and ankles, and under various conditions (eg, resting and during stress). The following systolic blood pressure values were consistently skipped by the device: 89, 119, 120, 124, 125, 130, 140, 141, 150, 160, 170, 180, 190, and 200 mm Hg. No skip pattern was detected for diastolic blood pressure. Pulse data, which were only available in the Hypertension Genetic Epidemiology Network Study, also showed the following skipped values: 95, 99, 103, 106, and 109 bpm. Consultation with the manufacturer, the Critikon Corporation, indicated that the use of an algorithm designed to improve the accuracy of the DINAMAP device prevents these values from being displayed. Assessment of the extent and direction of bias caused by the skipped values is difficult, given that the algorithm is proprietary. While the implications of the skipped values are not clear, it is important for clinicians and researchers to be aware of this feature. **(*Hypertension*. 2000;35:1032-1036.)**

Key Words: blood pressure monitoring ■ blood pressure determination ■ pulse

Automated blood pressure measurement devices are commonly used in both research and clinical settings. These devices are easy to use and have the potential to minimize biases introduced by human (technician) error.[1] In epidemiological studies, given that devices are properly calibrated, their use has the potential to increase standardization of measurements and thus comparability of data across time and study sites. One commonly used automated device is the DINAMAP (Critikon Corp).[2] Studies have demonstrated that blood pressure measurements taken with the DINAMAP are highly repeatable.[3,4] However, the reported findings on its correlation with other noninvasive blood pressure measurement techniques have been inconsistent.[5–11] There also is some debate in the literature as to the accuracy of measurements obtained with this device.[12,13]

In the course of analysis of DINAMAP-derived blood pressure data, it came to our attention that certain values were skipped in the distribution of systolic blood pressure (SBP) values. This led us to systematically review blood pressures measured by this device available from 3 large National Heart, Lung, and Blood Institute (NHLBI)-sponsored studies. The findings from our review are reported in this article.

Methods

Study Populations

DINAMAP data reviewed for this study were collected in the Atherosclerosis Risk in Communities (ARIC) study, the NHLBI Family Heart Study (FHS), and the Hypertension Genetic Epidemiology Network (HyperGEN) study, each supported by the NHLBI.[14,15,16]

The ARIC study includes a cohort study of middle-aged African American and white men and women sampled from 4 US communities (Forsyth County, NC; Jackson, Miss; suburban Minneapolis, Minn; and Washington County, Md) designed to investigate the causes and natural history of atherosclerosis.[14] At baseline (1987 to 1989), there were 15 792 participants. A variety of DINAMAP-derived blood pressure measurements were taken during the baseline examination including multiple sitting, supine, and standing blood pressures; in addition to brachial measurements, 2 measurements were also taken at the ankle. Details of the blood pressure measurement protocol are described elsewhere.[17] DINAMAP measurements also were obtained on participants who were reexamined during either visit 3 (1993 to 1995) or visit 4 (1996 to 1998). These included several brachial measurements and an ankle measurement.

The NHLBI FHS is a multicenter (Framingham, Mass; Forsyth County, NC; suburban Minneapolis, Minn; and Salt Lake City, Utah), biethnic population–based study of genetic and nongenetic determinants of cardiovascular disease risk factors, atherosclerosis, and coronary heart disease.[15] Phase 2 (1994 to 1995) of the FHS involved a clinical examination of members of 588 randomly

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selected families and 657 high-risk families. During this examination, DINAMAP blood pressure measurements were taken in both the ankle and the arms and in both the sitting and standing positions. Details of the study design and the blood pressure measurement protocol have previously been described.[15,18]

The HyperGEN study was designed to investigate genetic determinants of hypertension in African American and white men and women from 5 US communities (Birmingham, Ala; Framingham, Mass; Forsyth County, NC; suburban Minneapolis, Minn; and Salt Lake City, Utah).[16] Included in this study are data that were available as of December 1998: a random sample (≈900 participants) and hypertensive sibship pairs (≈2500 individuals). Multiple DINAMAP blood pressure measurements were taken in the seated, supine, and standing positions, under both resting and stress-provoking situations. Seated measurements were taken on both arms. Details of the study design and the blood pressure measurement protocol are described elsewhere.[16]

All participants in the ARIC, FHS, and HyperGEN studies gave written informed consent.

Blood Pressure Measurements

All blood pressure measurements examined in this study were taken with the use of a DINAMAP 1846-SX or a DINAMAP 1846-SX/P device. Its automated measurements were noninvasive and used an oscillometric technique to determine blood pressure values.[2] The maximum and minimum detectable SBP values were 245 and 30 mm Hg, respectively. For diastolic blood pressure (DBP), the maximum and minimum values were 210 and 10 mm Hg, respectively. In adults, during the first determination sequence, the cuff pressure was inflated to 178 mm Hg. If a participant's SBP exceeded this value, as indicated by the absence of a systolic value, the cuff was inflated to a higher inflation pressure (which did not exceed 250 mm Hg). A sensitive transducer measured both cuff pressure and pressure oscillations within the cuff. A stepped deflation technique, which was dependent on the interval between the participants' heartbeats, was used. The determination sequence was as follows: SBP, mean arterial pressure, DBP, and pulse. When diastolic pressure was determined or the cuff pressure fell to <7 mm Hg, the monitor deflated the cuff and analyzed the data, which was automatically stored on a microprocessor during each step of the measurement process. To avoid transcription errors, blood pressure and pulse values were downloaded from the DINAMAP to a personal computer. An exception was that in the FHS study, sitting blood pressure measurements were transcribed.

Analytic Technique

For each of the 3 studies, frequency distributions for all available DINAMAP-obtained SBP, DBP, and pulse (HyperGEN only) measurements were generated with the use of the SAS System.[19] Given that within each study the same DINAMAP model but different machines were used at each study site, all frequencies were initially stratified by study center. Statistics for each of the 3 indexes were visually inspected and omitted values were recorded. Values that occurred infrequently but were proximal to values that occurred with high frequencies were also recorded and further analyzed.

Results

The Table provides data on the number of SBP measurements taken, the number of participants who had SBP taken for each of the measurements, and information on the skip patterns detected for each of the 3 studies. In the baseline examination of the ARIC study, DINAMAP SBP measurements were taken on between 7367 and 15 171 participants. The following values (mm Hg) were not observed: 89, 119, 124, 125, 130, 140, 141, 150, 160, 170, 180, 190, and 200. The value 118 occurred in only 1 participant during the first standing SBP measurement. At ARIC visits 3 to 4, each SBP measurement was made on between 10 414 and 10 160 participants. Skipped values were the same as in the baseline visit, with the exception that 118 was not observed and that 140 appeared on 5 occasions. Further analysis indicated that this occurred only in 1 machine and that these occurrences were limited to 3 participants.

Data based on between 2026 and 2166 participants across 16 different SBP measurements were evaluated in the HyperGEN study. The following values were not observed: 89, 118, 124, 140, 141, 150, 160, 170, 180, 190, and 200. Two values occurred 1 time (119 and 130 mm Hg) and 1 value occurred 2 times (125 mm Hg); these occurred in the same study participant.

Analysis of FHS DINAMAP data based on between 1441 and 4283 participants across 9 different SBP measures revealed that the identical values were missing, as in ARIC and HyperGEN, except that at 1 study site 130 mm Hg occurred 2 times and 140 mm Hg occurred 1 time.

To provide a visual representation of the skip pattern, as well as to demonstrate the frequency of values immediately proximal to those values that did not occur, the Figure presents data from the first brachial SBP measurement taken at visit 1 of the ARIC study.

A similar assessment of all DINAMAP-derived DBP measurements was made. No skip pattern was detected for DBP (data not presented). DINAMAP-derived pulse data were readily available only in the HyperGEN study. Across >33 000 different measurements, the following pulse values did not occur: 95, 99, 103, 106, and 109 bpm.

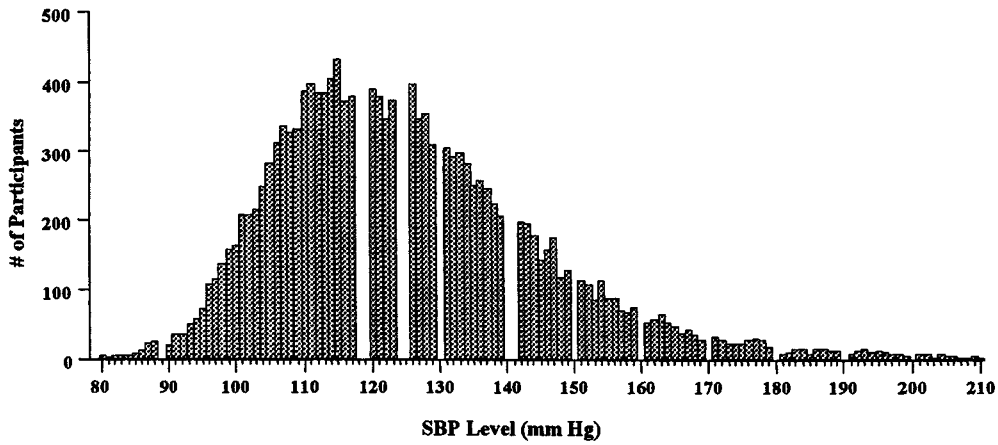
Discussion

Our findings, based on >367 000 separate DINAMAP measurements, indicate that there were 14 SBP values (89, 118, 119, 124, 125, 130, 140, 141, 150, 160, 170, 180, 190, and 200 mm Hg) that rarely or never occurred. The skip pattern for values of ≥150 occurred only at equal increments of 10 mm Hg, and in some instances 2 contiguous SBP values were skipped (eg, 118, 119 mm Hg); however, an overall pattern to the values skipped could not be discerned. In contrast, no DBP values were detected that were consistently skipped. Finally, an evaluation of pulse data based on measurements available from the HyperGEN study revealed that 5 values were not observed (95, 99, 103, 106, and 109 bpm).

Because the *DINAMAP Operation Manual*[2] does not refer to this phenomenon, the manufacturer of the DINAMAP equipment, the Critikon Corporation, was consulted. A member of the technical staff confirmed that the skip pattern we observed for SBP was known to the manufacturer of the DINAMAP. This pattern is reportedly the result of an algorithm developed to adjust oscillometric SBP to improve accuracy when compared with an intra-arterial reference. The application of the algorithm ostensibly adjusts for changes in the compliance of the vessel but leads to gaps in the SBP values that are consistent with the skip pattern that we observed. The extremely rare occurrence in our data of some of the values, which should not have occurred because of the algorithm, may have been due to observer error. This could occur when there was a failure in the connection between the DINAMAP and the computer, which led to a manual tran-

Summary of SBP Skip Pattern Noted in 3 NHLBI-Supported Studies

SBP Measurement	No. of Measurements	No. of Occurrences of SBP Values Listed													
		89	118	119	124	125	130	140	141	150	160	170	180	190	200
ARIC visit 1															
1st Sitting	7369	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2nd Sitting	7367	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1st Ankle	15 171	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2nd Ankle	14 969	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1st Brachial	15 261	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2nd Brachial	15 225	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1st Standing	14 680	0	1	0	0	0	0	0	0	0	0	0	0	0	0
2nd Standing	14 696	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3rd Standing	14 507	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4th Standing	13 266	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5th Standing	8406	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1st Supine	14 755	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2nd Supine	14 713	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3rd Supine	14 523	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4th Supine	13 101	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5th Supine	10 160	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ARIC visit 3/4															
Ankle	10 160	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Brachial	10 414	0	0	0	0	0	0	1	0	0	0	0	0	0	0
SBP 1	10 160	0	0	0	0	0	0	1	0	0	0	0	0	0	0
SBP 2	10 414	0	0	0	0	0	0	1	0	0	0	0	0	0	0
SBP 3	10 472	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SBP 4	10 472	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SBP 5	10 472	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SBP 6	10 472	0	0	0	0	0	0	1	0	0	0	0	0	0	0
SBP 7	10 472	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FHS															
Ankle	4242	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Arm 1	4283	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Arm 2	4256	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Arm 3	3960	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sitting	4194	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Standing 1	4113	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Standing 2	4097	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SBP 1	1442	0	0	0	0	0	1	0	0	0	0	0	0	0	0
SBP 2	1441	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HyperGEN															
Sitting 1	2165	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sitting 2	2166	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sitting 3	2166	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Sitting 4	2144	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sitting 5	2144	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Sitting 6	2143	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Supine	2144	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Standing 1	2077	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Standing 2	2075	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Math 1	2082	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Math 2	2078	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Math 3	2037	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Math 4	2029	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grip 1	2032	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grip 2	2029	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Grip 3	2026	0	0	0	0	0	0	0	0	0	0	0	0	0	0



Frequency distribution of values for first brachial SBP measurement, visit 1 of ARIC Study.

scription of the blood pressure values. Another possibility is that incorrect cuff placement and/or slippage during the blood pressure measurement (which would be most common in obese participants) could have led to variations between measures that exceeded the machine tolerance and thus caused a failure in the algorithm.

The adjustment algorithm is not applied to DBP measurements, which is consistent with the absence of a skip pattern for DBP in our data. Skipped values for pulse rates are caused by resolution limitations according to the manufacturer, particularly at higher heart rates. The DINAMAP is programmed to improve accuracy of its output for pulse rate by choosing what it senses to be the best period during the blood pressure determination. Given the consistency of the skip pattern we observed for heart rate, it is highly unlikely that any of the skipped values seen in our data occurred as the result of chance or technician error.

The algorithm used in the DINAMAP is proprietary. Thus, it is difficult to assess the extent and direction of biases introduced as the result of the skipping of certain values. Two of the skipped SBP values (140 and 141 mm Hg) are in a range relevant to a cut-point for classification as “hypertension.” Thus, depending on whether the algorithm adjusted values upward or downward, individuals could be incorrectly categorized as having or not having hypertension. It does not appear that skipped values were consistently assigned to adjacent SBP values because there was not a strong or consistent excess in the frequency of SBP values immediately contiguous to or in the vicinity of the skipped value (see Figure). Given the variable nature of blood pressure and that in both clinical and research settings a diagnosis of hypertension is usually based on multiple measurements, any potential bias caused by a skipped value should be reduced.

Efforts to assess the accuracy of the DINAMAP device are often based on comparisons with other indirect measurements obtained from a standard mercury sphygmomanometer (eg, References 7 and 9). Yet, measurements with the latter device may have limited repeatability[20,21] and can be prone to substantial biases caused by digit preference.[22–25]

The gold standard for determination of blood pressure is by direct measurement of intra-arterial pressure with a catheter.[26] The DINAMAP was developed with the use of direct measurements of central aortic pressure as a reference. Validation studies that have compared the performance of the DINAMAP with this “gold standard” generally have found accuracy to be within established limits of acceptability,[27,28] and reliability studies have found its repeatability high.[3–5] Thus, even in light of the skip patterns currently reported, use of the DINAMAP or other automated devices may be preferable to a mercury sphygmomanometer, particularly in large or multicenter epidemiological studies where the use of multiple technicians makes it difficult to obtain standardized blood pressure measurements. Similarly, such devices may be the better choice in situations in which repeated, self-administered measurements of blood pressure are required (eg, see Reference 29).

In summary, we have identified a clear and distinct skip pattern in SBP and pulse values obtained from the DINAMAP automated device. To the best of our knowledge, this has not previously been documented in the literature. While the implications of the skipped values are not clear, it is important for both clinicians and researchers to be aware of this feature.

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