The Dinamap 1846SX automated blood pressure recorder: comparison with the Hawksley random zero sphygmomanometer under field conditions

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Abstract

Study objective—The aim was to compare the performance of the Dinamap 1846SX automated oscillometric blood pressure recorder with that of the Hawksley random zero sphygmomanometer during use under field study conditions.

Design—Two independent within subject measurement comparisons were made, one in adults and one in children, each conducted in three stages over several months while the Dinamap instruments were being used in epidemiological field surveys.

Setting—The studies were done in outpatients clinics (adults) and primary schools (children).

Participants—141 adults (20–85 years) and 152 children (5–7 years) took part.

Measurements and main results—In adults a pair of measurements was made with each instrument, the order alternating for consecutive subjects. In children one measurement was made with each instrument, in random order. Measurements with the Dinamap 1846SX were higher than those with the random zero sphygmomanometer both in adults (mean difference 8.1 mm Hg; 95% CI 6.5 to 9.7 mm Hg) and in children (mean difference 8.3 mm Hg; 95% CI 6.9 to 9.7 mm Hg). Diastolic measurements were on average very similar both in adults and in children. The results were consistent at all three stages of both studies. The differences in systolic measurement were independent of blood pressure level. However, the extent of agreement in diastolic pressure depended on the diastolic blood pressure level; in both studies Dinamap diastolic measurements were higher at low diastolic pressures while random zero diastolic measurements were higher at high diastolic pressures.

Conclusions—Systolic measurements made with the Dinamap 1846SX instrument are not directly comparable with those of the Hawksley random zero sphygmomanometer and are unlikely to be comparable with those of earlier Dinamap models. These differences have important implications for clinical practice and for comparisons of blood pressure measurement between epidemiological studies. However, the consistency of measurement by the Dinamap 1846SX over time suggests that the instrument may have a place in standardised blood pressure measurement in the research setting.

The use of the sphygmomanometer in standardised blood pressure measurement raises several potential problems. Blood pressure measurement may vary between observers,¹ and observer performance may vary over time, despite observer training.^{2,3} Modified sphygmomanometers^{4,5} may reduce digit preference but do not necessarily eliminate observer bias in blood pressure measurement. By standardising the technical aspects of measurement and recording, automated blood pressure recorders may reduce these variations in blood pressure measurement. However, insufficient information is available on the performance of many of these instruments.⁶ The Dinamap automated blood pressure recorder (Critikon Inc), which uses the oscillometric method,⁷ is being increasingly used by investigators. The earlier Dinamap devices, particularly the 845 and 847 series, have been extensively studied in comparison with direct intra-arterial measurement^{7–17} and the mercury sphygmomanometer.^{18–23} However, relatively little attention has been given to the more recent Dinamap series.^{24,25} Moreover, few data are available on the accuracy of the instrument at different blood pressure levels²⁶ and on the performance and reliability of the Dinamap in population based surveys. We report the results of two separate studies designed to compare the performance of the more recent Dinamap 1846SX automated blood pressure recorder with the Hawksley random zero sphygmomanometer. These studies, one in adults and one in children, were both carried out over several months while the Dinamap instruments were being used in two large population surveys.^{27,28}

Methods

STUDY IN ADULTS

Subjects aged between 20 and 85 years attending a medical outpatient clinic were invited to participate. A total of 154 subjects took part. The study took place in three stages over a total of seven months. All measurements were made by two experienced observers, each of whom examined approximately half the subjects on each occasion. Both observers received training in auscultatory blood pressure measurement² less than a week before the beginning of each stage of the study. Observer performance was examined after each training session with a standard test tape²; all observers showed an average error within the recommended limits of one second (2 mm Hg) in both systolic and diastolic recordings throughout the study. All measurements were made on the right arm with the subject

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seated after 5 minutes' rest. Four consecutive blood pressure measurements were taken at one minute intervals on each participant, two with the Dinamap 1846SX and two with the Hawksley random zero sphygmomanometer. The order in which the instruments were used was alternated for each subject, ensuring that numbers were balanced for each session. The Dinamap 1846SX had an initial inflation pressure of 180 mm Hg and all results were recorded directly onto a printed output. A standard Hawksley random zero sphygmomanometer was used with an initial inflation pressure of 200 mm Hg. Diastolic pressure was recorded at the point of disappearance of Korotkow sounds (Phase V). The cuff sizes recommended by the manufacturer, which conform to the guidelines of the American Heart Association,²⁹ were used on each occasion with both instruments.

STUDY IN CHILDREN

Children aged between five and seven years and attending three primary schools were invited to take part in this study. A total of 152 subjects took part. The study took place in three stages over a period of 10 months. All measurements were made by two experienced observers, each of whom made approximately half of the paired blood pressure measurements on each occasion. Training and testing in auscultatory blood pressure measurement was carried out as in the adult study.² All measurements were made on the right arm with the subject seated after 5 minutes' rest. Two consecutive blood pressure measurements were taken one minute apart on each participant, one with a Dinamap 1846SX and one with a Hawksley random zero sphygmomanometer. The order of measurement was randomly allocated and balanced for each session. Both instruments were distinct from those used in the adult study. The Dinamap 1846SX was of identical specification; the Hawksley random zero instrument was fitted with a 20 mm Hg cam, enabling a lower initial inflation pressure of 180 mm Hg to be used. Diastolic pressure was recorded at the point of muffling of Korotkow sounds (Phase IV) because of the difficulty in recording Phase V accurately in children.²⁹ The cuff bladder size used for each instrument followed the recommendations of Prineas and colleagues,³⁰ closely related to those of the American Heart Association,²⁹ to ensure that cuff bladder length was at least 90% of arm circumference and the cuff bladder width at least 120% of arm diameter in every case. Two sizes of cuff were available for use with each instrument in the study; cuff bladder dimensions for the Dinamap were 15 cm x 9 cm (child), 22 cm x 12 cm (adult), and for the Hawksley were 18 cm x 9 cm (child), 23 cm x 12 cm (adult). In a separate study, a systematic difference in blood pressure measurement between the two cuffs used with each instruments was observed, with child cuffs recording systematically higher blood pressures than the adult cuffs.³¹ Accordingly, all results were standardised to the child cuff size as described.³² However, the results presented here are very similar whether or not such standardisation is employed.

USE OF INSTRUMENTS IN FIELD STUDIES

Between the first and third set of comparisons described here, both Dinamap instruments were used in epidemiological field surveys, each instrument making more than 10 000 blood pressure measurements and being calibrated daily during use against standard mercury columns at 0, 50, 100, 150, and 200 mm Hg. No evidence of drift in static calibration requiring adjustment was detected in either of the two instruments. In the adult study, the instrument failed to record measurements in only two subjects out of 2615, while in the child study measurements were obtained in all but seven of 4116 subjects (0.17%), usually as a result of the child moving. The Hawksley instruments were held specifically for the comparative studies over this period and made no other measurements.

STATISTICAL METHODS

Mean differences between instruments—In the adult study results are based on the means of the pairs of readings carried out with each instrument in each subject; in the study of children, results are based on single readings. The comparisons between instruments reported are all based on within subject differences, presented as Dinamap measurement minus Hawksley measurement throughout.

Blood pressure level—Blood pressure level for each subject is calculated as the mean of all readings carried out in that subject using both Dinamap and Hawksley instruments. Adjustments for the order in which the machines were used for each subject were made because blood pressure tends to fall with successive measurements. Relationships between the difference between measurements by the two instruments and the mean recorded blood pressure were examined using standard multiple linear regression techniques. Comparisons of measurements at different sessions were examined using a one way analysis of variance.

Results

Results are presented for all 152 subjects in the children's study. In the adult study results are presented for 141 (93%) subjects. Thirteen subjects with incomplete data have been excluded. The characteristics of subjects allocated to different order of measurement are presented in the table. In the adult study there was a difference in the age and sex distribution of the two groups, with subjects measured first with the Hawksley

Characteristics of subjects by order of measurement. Values are mean (SE).

	Dinamap first	Hawksley first
Adult study		
Number	71	70
Age (years)	51.8 (1.9)	57.0 (2.0)
Sex (% male)	45	59
Observer (% each)	51/49	56/44
SBP (mean of both readings)	135.9 (3.0)	135.8 (2.6)
DBP (mean of both readings)	78.4 (1.6)	76.4 (1.5)
Child study		
Number	74	78
Age (years)	6.32 (0.08)	6.31 (0.08)
Sex (% male)	52	54
Observer (% each)	50/50	47/53
SBP (mean of both readings)	96.4 (1.2)	96.4 (1.1)
DBP (mean of both readings)	58.2 (0.8)	57.1 (0.7)

SBP = systolic blood pressure; DBP = diastolic blood pressure

being older and having a greater predominance of males. However, adjustment for these factors had no important effect on the measurement differences between the instruments. The characteristics of the randomised groups in the study of children are very similar. All results were examined for each observer separately. No important differences between observers were found and results are therefore presented without observer adjustment.

MEAN SYSTOLIC PRESSURE DIFFERENCES BETWEEN INSTRUMENTS AND THEIR RELATIONSHIPS TO SYSTOLIC BLOOD PRESSURE LEVEL

Systolic blood pressure measurements were markedly higher with the Dinamap instrument than the Hawksley instrument both in adults (mean difference 8.1 mm Hg; 95% CI 6.5 to 9.7 mm Hg; $p < 0.0001$) and in children (mean difference 8.3 mm Hg; 95% CI 6.9 to 9.7 mm Hg; $p < 0.0001$).

The relationships between these systolic blood pressure differences between instruments and systolic blood pressure level are presented in figure 1. Systolic differences between instruments are not importantly influenced by blood pressure level either in adults or in children; regression coefficients, representing the change in systolic blood pressure difference between instruments in mm Hg for each 1 mm Hg change in systolic blood pressure level, are 0.046 (standard error 0.035, $p = 0.20$) for adults and 0.013 (standard error 0.072, $p = 0.85$) for children.

MEAN DIASTOLIC PRESSURE DIFFERENCES BETWEEN INSTRUMENTS AND THEIR RELATIONSHIPS TO DIASTOLIC BLOOD PRESSURE LEVEL

Mean differences in diastolic pressure between the Dinamap and Hawksley instruments are very small, both in adults (mean difference 0.2 mm Hg; 95% CI 1.2 to 1.6 mm Hg) and in children (mean difference -0.2 mm Hg; 95% CI 1.8 to 1.4 mm

Hg), suggesting a high level of overall agreement in diastolic pressure between the instruments. The relationships between diastolic differences between instruments and diastolic blood pressure level are presented in figure 1. There appears to be a negative relationship between blood pressure level and blood pressure difference between instruments; at high diastolic pressure levels Dinamap readings are lower than Hawksley readings, whereas at low diastolic pressure levels the reverse is true. This appears to be the case in both the study of adults and the study of children. Regression coefficients, which represent the change in diastolic blood pressure difference between instruments (mm Hg) for each mm Hg change in diastolic blood pressure level, are -0.189 (SE 0.051, $p = 0.0003$) for adults and -0.324 (SE 0.102, $p = 0.002$) for children. The strengths of these relationships suggest that a 10 mm Hg rise in diastolic blood pressure level is accompanied by a fall in Dinamap-Hawksley differences of 1.9 mm Hg for adults and 3.1 mm Hg for children. The slopes of these relationships between blood pressure level and measurement differences are not markedly different in the two studies (test for difference between slopes, $p = 0.25$). However, the positions of these slopes are quite different, as indicated by the difference between the two studies in the diastolic blood pressure level at which there is complete agreement between instruments, 79 mm Hg in the adult study and 57 mm Hg in the child study. This difference is highly statistically significant ($p < 0.001$).

BLOOD PRESSURE DIFFERENCES BETWEEN INSTRUMENTS OVER TIME

The differences in blood pressure measurement between the Dinamap and Hawksley instruments at each of the three examination sessions are presented in fig 2. Variations in measurement differences between sessions were more marked

Figure 1 Blood pressure level and differences in blood pressure measurement between Dinamap 1846SX and Hawksley instruments. Systolic and diastolic differences (Dinamap-Hawksley) are presented for individual subjects in both adult and child studies. SBP=systolic blood pressure; DBP=diastolic blood pressure.

Figure 2 Differences in blood pressure measurement between Dinamap 1846SX and Hawksley instruments (Dinamap-Hawksley) by session of examination. Means and 95% confidence intervals are shown. SBP=systolic blood pressure; DBP=diastolic blood pressure.

for systolic than for diastolic pressure in both adults and children. In the case of adults, mean Dinamap-Hawksley systolic differences increased by a total of 2.8 mm Hg between the first and third sessions. However, these changes could easily be due to chance ($p=0.42$). There was also an increase in systolic differences between the first and third stages of the children's study (by 3.5 mm Hg) but although the difference approached the conventional level of statistical significance ($p=0.064$) there was no indication of a consistent trend. For diastolic pressure the agreement of Dinamap and Hawksley measurements was extremely consistent over the period of examination in both adult and child studies.

Discussion

This report is among the first describing the performance of a contemporary automated oscillometric blood pressure recorder, the Dinamap 1846SX, under field survey conditions. The populations studied encompass a wide range of ages and blood pressure levels, with over 10% of adult subjects being hypertensive (systolic blood pressure ≥ 160 mm Hg or diastolic blood pressure ≥ 95 mm Hg).

OVERALL DIFFERENCES BETWEEN DINAMAP AND HAWSKLEY INSTRUMENTS

The Dinamap 1846SX recorded systolic pressures consistently higher than those obtained by the Hawksley instrument in both adults and children. Diastolic pressures, by contrast, showed a high level of overall agreement between instruments. Although these results are based on studies using a single instrument in each case, the observations of the two studies are strikingly consistent. Placed in the context of previous reported comparisons between Dinamap and auscultatory instruments (fig 3), the results are in close agreement with the one previous study involving the Dinamap 1846SX,²⁵ and also with the results of a study of the Dinamap 8100, a closely related model.¹⁸ The most striking feature of this figure is that whereas systolic measurements made by the earlier Dinamap 845 model match auscultatory measurements closely, those of the 8100 and 1846SX exceed auscultatory measurements by several millimetres. Different reference sphygmomanometers were used in these studies, with some using the standard mercury instrument and others the Hawksley random zero instrument. However, the

Figure 3 Review of published comparisons of systolic and diastolic blood pressure measurement between Dinamap oscillometric recorders and sphygmomanometers. The name of the first author, the number of the Dinamap model, and the type of sphygmomanometer (SS=standard mercury sphygmomanometer; RZ=random zero sphygmomanometer; MM=mercury manometer) are given in each case. The mean Dinamap-sphygmomanometer difference, with 95% confidence intervals where possible, is shown for each study. ch=child; ad=adult.

differences shown in fig 3 appear to be independent of the type of reference sphygmomanometer used and the findings are therefore unlikely to be explained by the differences in blood pressure measurement between the standard and random zero instruments which have been reported.³²⁻³⁴ The most likely explanation of the findings in fig 3 is that systolic measurement by the Dinamap 1846SX and 8100 models is not comparable with that of the earlier 845 model, possibly as a result of changes in programming in the newer models. For diastolic pressure, by contrast, measurements made by all Dinamap models agree closely with those of sphygmomanometers (fig 3). The relationship between Dinamap 1846SX measurement and direct intra-arterial measurements remains uncertain. Only one study, conducted in premature neonates, has compared Dinamap 1846SX measurements with direct intra-arterial measurement.²⁴ In that study, the Dinamap 1846SX underestimated directly measured systolic pressure by an average of 4.9 mm Hg, a finding which contrasts with earlier reports on the 845 and 847 models, which showed good agreement with direct intra-arterial measurement.⁹⁻¹¹ These contradictory findings emphasise the need for further evaluation of the Dinamap 1846 SX, particularly in relation to direct intra-arterial pressure measurement.

INSTRUMENT DIFFERENCES IN BLOOD PRESSURE MEASUREMENT AND THEIR RELATIONSHIP TO BLOOD PRESSURE LEVEL

A negative relationship between diastolic pressure level and diastolic differences between the two instruments was observed in both adult and child studies. This has not previously been reported with the Dinamap 1846SX,²⁵ although an earlier study suggested that the Dinamap 845 might overestimate pressures at low blood pressure levels.¹⁷ The basis for the finding remains uncertain, but it seems unlikely that diastolic blood pressure level per se is responsible. The marked difference in the position of the slopes relating diastolic blood pressure level and instrument differences in the adult and childhood studies argues strongly against a uniform relationship between blood pressure level and instrument differences. This suggests that a factor other than blood pressure level is responsible for the relationship.

CONSISTENCY OF DINAMAP PERFORMANCE OVER TIME

The Dinamap instrument proved robust, with no mechanical or electronic component failures despite frequent dismantling and removal. However, the condition of the rubber O-rings sealing the pressure hose junctions could deteriorate quite rapidly with repeated cuff changes and dismantling of the instrument and careful monitoring was required to ensure that these remained in satisfactory condition. The static calibration testing of both instruments remained stable throughout the periods of study. Moreover, the studies described in this report provide no strong evidence of drift in blood pressure measurement with either instrument,

despite extensive use, an experience consistent with that of Ellison *et al* with the Dinamap 845.¹⁹

IMPLICATIONS FOR USE OF THE DINAMAP 1846SX INSTRUMENT

The large systematic difference in systolic measurement between the Dinamap 1846SX and the random zero sphygmomanometer, exceeding the 5 mm Hg limits advocated by the Association for the Advancement of Medical Instrumentation,³⁵ could lead to the overdiagnosis of hypertension if systolic criteria based on auscultatory measurements are applied to measurements made by the Dinamap 1846SX. The results of this study therefore suggest that the Dinamap 1846SX is unsuitable as a direct substitute for the sphygmomanometer in a clinical setting. In the research setting (both in population studies and clinical trials), the ability to make consistent measurements in all circumstances is particularly important. Our data suggest that the Dinamap 1846SX fulfils this criterion. Systematic differences in blood pressure measurement from the standard sphygmomanometer are of less importance in the research context because the main outcome of a research investigation will normally be based on blood pressure comparisons conducted *within* the study. However, comparisons *between* studies using the Dinamap 1846SX and other instruments are inadvisable unless differences in measurement between these instruments are taken into account.

Addendum—Since this paper was prepared, another report has provided evidence of systematic differences in systolic blood pressure measurement (and possibly also diastolic measurement) between the Dinamap 1846SX and auscultatory instruments.³⁶

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