Accuracy of the Dinamap Portable Monitor, model 8100: a review of the evidence for accuracy

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Conventional measurement of blood pressure is fraught with many potential errors [1]. Automated blood pressure measuring devices remove observer bias and permit repeated blood pressure measurements at predetermined intervals, features which have obvious attractions in clinical practice and in hypertension and epidemiological research. However, such devices, which can be expensive, must be shown to be as accurate as the conventional technique which they are designed to replace [2]. A number of Dinamap models are available [3], the Dinamap Portable Monitor, Model 8100 (Critikon, Tampa, Florida, USA), being one of the most popular automated devices used in clinical practice and in hypertension research, despite reports demonstrating that it is inaccurate in certain clinical circumstances. We therefore decided to review the literature on the Dinamap 8100. Ten papers [4–13] concerned specifically with the accuracy of this model were identified; they all acknowledged its inaccuracy but not all reached the same conclusions regarding the influence of such inaccuracy in practice.

The first study of the Dinamap 8100, by Ormstein *et al.* [4] in 1988, showed that it overestimated systolic blood pressure by 7.6 mmHg and diastolic blood pressure by 0.7 mmHg. Goonasekera and Dillon [5] also found that the Dinamap 8100 overestimated systolic blood pressure (by an average of 6.45 mmHg), but that it underestimated diastolic blood pressure by an average of 10.77 mmHg. These two studies assessed the Dinamap 8100 against the Hawksley random zero sphygmomanometer rather than a standard mercury sphygmomanometer, thereby making comparison of the results difficult, as the Hawksley sphygmomanometer has been shown to underestimate blood pressure and is no longer recommended for validation studies [14,15]. The Dinamap 8100 was assessed against direct intra-arterial blood pressure in the opposite arm during the transfer of critically ill patients to hospital [6]: it underestimated systolic blood pressure and overestimated diastolic blood pressure, leading the authors to conclude that the device should not be substituted for direct blood pressure measurement in critically ill patients. The differing methodology and the circumstances of measurement in this study again preclude comparisons with other studies.

In an attempt to determine if the Dinamap 8100 would enhance precision and thereby reduce sample size requirements in clinical trials of blood-pressure-lowering drugs, Appel *et al.* [7], using a standard mercury sphygmomanometer for comparison, found that the device underestimated diastolic pressures. Likewise, in a study in pregnancy [8], the Dinamap 8100 underestimated diastolic pressure by 9.8 mmHg, leading the authors to suggest adding a correction factor of 10 mmHg to the diastolic pressures recorded by the Dinamap 8100 during pregnancy. In a field study in children [9], the Dinamap 8100 underestimated diastolic blood pressure, leading to the conclusion that the mercury sphygmomanometer was the device of choice for epidemiological studies in children.

In 1993 we evaluated the Dinamap 8100 [10] according to the protocol of the British Hypertension Society (BHS) [16], which grades accuracy from A (very good) to D (very poor). The Dinamap 8100 underestimated systolic blood pressure by 0.71 mmHg and diastolic blood pressure by 7.6 mmHg, achieving a Grade B for systolic, with 66% of pressures being within 5 mmHg of the mercury sphygmomanometer, and only a D grade for diastolic blood pressure, with less than 50% of pressures being within 5 mmHg of the mercury standard. Looked at another way, diastolic pressure measured by the Dinamap 8100 differed from the mercury standard by more than 5 mmHg in 53% of comparisons, with 26% of comparisons differing by more than 10 mmHg and 12% by more than 15 mmHg. If the criteria for accuracy of the Association for the Advancement of Medical Instrumentation [17] are applied to these data, the Dinamap 8100 fulfills the criteria for systolic but not for diastolic blood pressures. On the basis of these results, we concluded that the diastolic error was unacceptable in clinical practice and urged the manufacturers to modify the algorithm [10].

Our validation [10] was commissioned on behalf of the UK Department of Health by the Office of Population Censuses and Surveys (OPCS) which was (and still is)

conducting a continuous survey to monitor the health and nutrition of the adult population of England [11]. The Dinamap 8100 was chosen for this study by a 'Technical Advisory Panel on 'the basis of studies in both Britain and the United States which suggested that it, or a very similar instrument (the Dinamap 1846SX), measured blood pressure consistently over time' [12]. It seems that the Dinamap 8100 was purchased on the basis of this recommendation, but shortly afterwards the OPCS deemed it prudent to check independently the accuracy of the Dinamap 8100. We were asked to perform a full validation according to the BHS protocol and, as the Dinamap 8100 was already in use in the Health Survey, the OPCS collaborated in the validation, performing the first three phases of the BHS protocol. However, when the results were being prepared for publication, the OPCS participants declined to have their names listed among the authorship.

Shortly after this validation was completed, the OPCS published *Health Survey for England 1991* [11] in an appendix of which the results of our validation were presented with an additional analysis showing the mean difference between the Dinamap 8100 monitor and the standard mercury sphygmomanometer. The conclusions in this appendix were that, although the Dinamap 8100 had been shown to underestimate diastolic blood pressure because 'the difference between the monitors was constant across the blood pressure range', it was acceptable to continue using the Dinamap 8100 'in an epidemiological setting such as the Health Survey where the primary aim is to make comparisons across time, place and person' [11]. It was recommended, however, that a further study should be carried out, and the Dinamap 8100 Calibration Study [12] was set up 'to compare the performance of the Dinamap 8100 oscillometric blood pressure monitor with an auscultatory monitor, the mercury sphygmomanometer, under field survey conditions similar to those which exist in the Health Survey for England'. The results of this study were published in an official government report in 1994 [12]. Neither this nor the earlier report [11] are indexed in the current literature (as would be the case with a journal publication) and they have only recently come to our attention. The results of the second OPCS study [12] showed that systolic blood pressure was significantly higher when read with the Dinamap 8100 than with the mercury sphygmomanometer (mean difference +7.9 mmHg), with the diastolic blood pressure reading lower than the mercury standard (mean difference −1.8 mmHg). This difference reaching statistical significance in men and women aged 16–34 and in all women. The difference between the two devices was not consistent across mean blood pressure levels for either systolic or diastolic blood pressures. On the basis of these results the author of the report recommended that 'comparison of blood pressure levels from the Health Survey for England with other epidemiological studies which have used different measuring devices remains problematic and should be done with caution' [15]. Yet a conclusion was reached which is the antithesis of the above recommendation and runs contrary to the data from other studies: 'The Dinamap 8100 monitor provides a reliable estimate of blood pressure for the purposes of a large epidemiological survey like the Health Survey for England. This means that the results of the Survey can be used to establish baseline figures for the population and to monitor trends over time and make comparisons between subgroups of the population' [11].

With regard to the continued use of the Dinamap 8100 in the Health Survey of England (and in spite of two studies sponsored by the Department of Health, confirming the inaccuracy shown by others), we can only endorse what has been said on many occasions, namely that only those devices that have been validated independently should be used in research and practice [18,19]. If a particular device seems appropriate for a planned study but has not been independently validated, then the manufacturers should be asked to have such a validation performed before the study begins. The use of the Dinamap 8100 in a study of the magnitude of the Health Survey of England raises serious questions about the integrity of the data. Indeed, one of the preconditions of the study is that the Department of Health 'must be confident that any changes in [blood pressure] levels over time are due to real changes in the population and are not changes due to inconsistencies between the measuring devices or between those taking the measurements' [12]. It seems to us that, at best, the data may indicate trends in the population blood pressure, but comparisons between populations and between subgroups within those populations will not be valid.

This review of the literature endorses the conclusion we reached in 1993 [10], namely that the Dinamap Portable Adult/Pediatric and Neonatal Vital Signs Monitor, model 8100, because of its inaccuracy in measuring diastolic blood pressure, cannot be recommended for blood pressure measurement in adults in circumstances where accuracy is desired. The apparent indifference of the manufacturer of a popular blood pressure measuring device to a number of studies demonstrating its inaccuracy in measuring diastolic blood pressure is a cause for concern, but more disturbing is the paradox of the continuing successful marketing of the device despite these adverse reports.

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