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Special Feature

What is a normal blood pressure on ambulatory monitoring?

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Introduction

An operational threshold for making clinical decisions based on ambulatory blood pressure monitoring must be defined. This requires that the relationship between the ambulatory pressure and the incidence of cardiovascular complications be clarified beyond present understanding. In addition the distribution of the ambulatory blood pressure must be better characterized in various conditions and populations and compared with the centrality and spread of the conventional blood pressure under similar circumstances. Along these lines, several large-scale epidemiological studies in well-defined professional groups [1,2], in normotensive and hypertensive subjects [3–6], and in the population at large [7–16] have been published recently or are under way.

The average ambulatory pressure in normotensive subjects

Several smaller studies have described the ambulatory blood pressure in healthy subjects or in patients referred to specialized clinics to exclude the diagnosis of hypertension (for review, see reference [3]). In these reports the average systolic blood pressure over the whole day ranged from 111 to 124 mmHg, the daytime averages ranged from 115 to 128 mmHg and the night-time means from 99 to 111 mmHg; the corresponding ranges for the diastolic blood pressure means embraced 59 and 79 mmHg, 63 and 85 mmHg and 51 and 70 mmHg respectively [3].

In a Belgian population study [15], which included 1057 randomly selected subjects, of whom 328 were hypertensive, the participation rate was 69%. In all 1057 subjects the 24-h and the day- and night-time pressures averaged 119/71, 125/77, and 108/62 mmHg respectively. These values were almost identical to those noticed in a cohort of Irish bank employees (118/72, 124/78, 106/61 mmHg) [2]. In contrast they tended to be somewhat lower than in a random sample of a rural Japanese community (122/71, 127/75 and 112/64 mmHg respectively) [7,17]. However, the Japanese subjects were substantially older (59 years) than the Belgian (50 years) and Irish (36 years) [2] participants.

In the Belgian study the conventional compared with the daytime blood pressures were 3.5/1.5 mmHg lower in 729 normotensive people, but 11.6/4.5 mmHg higher in 328 hypertensive patients. Similar trends were also observed in the International Database [5,18]. Observer bias and arousal of the patients *vis-à-vis* the person measuring the conventional blood pressure, i.e. the so-called white coat effect [19], explain why in hypertensive patients the clinic pressure is usually higher than the daytime ambulatory pressure. The daytime ambulatory pressure is recorded during regular activities, when the blood pressure may be slightly elevated due to physical or psychological stress. The conventional pressure is usually measured in relaxed conditions after a few minutes rest. This may explain why in normotensive people, who by definition cannot have a pronounced white coat effect, the daytime ambulatory pressure is generally [5,18] a few mmHg higher than the conventional pressure.

Because in addition to the daytime pressures, also the low night-time pressures are averaged to calculate the 24-h pressures, the latter must be lower than the conventional measurements in both normotensive and hypertensive subjects. As suggested by others [20], the 24-h blood pressures should therefore not be employed to assess the white coat phenomenon.

How to determine operational thresholds?

In cross-sectional studies, the ambulatory blood pressure is positively related to left ventricular mass (for

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review, see reference [21]), an independent predictor of cardiovascular risk [22], and to other signs of target organ damage (for review, see reference [23]). Moreover, repeated semiautomated [24, 25] or fully automated [26,27] blood pressure measurements outside the hospital are more closely related to the incidence of cardiovascular complications than conventional blood pressure readings. In spite of these observations [24–27], the consensus prevails [28] that more prospective studies on the prognostic significance of ambulatory measurements are required in order to define meaningful thresholds for the clinical application of blood pressure monitoring. In addition, controlled clinical trials should be mounted in order to prove that it is indeed worthwhile to complement conventional sphygmomanometry with ambulatory monitoring in terms of cost-effectiveness, the patients' quality of life and their short-term and long-term outcomes [29].

Several prospective studies to clarify the prognostic significance of ambulatory blood pressure measurement are under way [30–34]. Pending confirmation by these prospective studies, several preliminary proposals for a reference frame for ambulatory monitoring have been published [2,3,5,35–37]. Most of these proposals first identified people who were normotensive as judged by conventional sphygmomanometry, i.e. the gold standard in clinical practice, and then defined the upper limits of the ambulatory measurements in these normotensive groups. This approach has the advantage of building on the vast experience, which over the past decades has accrued with conventional sphygmomanometry. Indeed, observational studies [38] as well as clinical outcome trials [39] have established beyond any doubt that normotensive compared with hypertensive subjects, in the absence of other risk factors, have a low cardiovascular risk profile. In this respect the upper limits of the distribution of the ambulatory measurements in normotensive subjects represent more than just statistical boundaries, but they are also meaningful from a clinical perspective.

The ambulatory blood pressure, like the conventional blood pressure, is not normally distributed in the population. In the Belgian study [15] the distributions of the ambulatory measurements stayed non-Gaussian even when the hypertensive patients were removed from the analysis. In general, taking the mean and adding twice the standard deviation may overestimate the high-end values in a non-normal distribution and may therefore be less suited to describe the upper tail of a blood pressure distribution. For instance, in the normotensive subjects included in the International Database [5], the mean plus two standard deviations for the systolic pressure on conventional measurement was 143 mmHg, while for the diastolic pressure it was 91 mmHg. In reality, all conventional readings had not exceeded 140 and 90 mmHg respectively. In a recent meta-analysis on the ambulatory blood pressure in normotensive subjects, using the mean plus two standard deviations was the only practicable approach of estimating the upper end of the distributions, because other statistics had been rarely reported in the published papers [3]. However, in large population studies, in which enough subjects have been enrolled in order to avoid the sampling error, which may flaw smaller studies, non-parametric statistics such as the 90th or 95th percentiles constitute the preferred way to delineate the upper tail of the non-normal blood pressure distributions.

Some experts have suggested that a definition of normality based on the 5th—95th percentile interval would only be acceptable for tightly distributed variables, such as serum sodium, but not for skewed measurements, such as blood pressure [40]. However, percentiles are non-parametric statistics, which only require that a set of data be arranged in order of magnitude without implying any assumption on the shape of the underlying distribution. Thus, whether applied to serum sodium or blood pressure, percentiles have exactly the same meaning. The use of the 95th percentile for defining normality has also been criticized, because if applied to the general population, by definition 5% of all individuals must have an abnormally elevated blood pressure [40]. However, in several large-scale studies [2,5,15,35–37], the percentiles used to derive a reference frame for ambulatory monitoring were determined not in all subjects, but only in normotensive subjects. Obviously the latter approach does not lead to an artificial 5% prevalence of abnormally elevated ambulatory blood pressures in the population at large.

A proposal for operational thresholds

The most prominent feature of the larger studies on ambulatory monitoring [2,3,5,7,10,11,18,41,42] is their striking concordance in the reported thresholds for the ambulatory pressures, be it the means plus two standard deviations or the 95th percentiles (for review, see reference [15]). Averaging the 95% percentiles in the normotensive subjects and rounding the resulting boundaries downwards or upwards to the nearest value ending in 0 or 5, may produce working definitions of normality for ambulatory monitoring, which can be easily remembered. Following these procedures, the upper limits of normotension, calculated by rounding downwards, would be 130/80 mmHg for the 24-h pressures and 135/85 and 120/70 mmHg for the day- and night-time pressures. Abnormality, obtained by rounding upwards, would be pressure levels equal to or 135/85, 140/90, and 125/75 mmHg, respectively (Table 1). These preliminary threshold values do not take into consideration gender and age. However, the boundaries currently in use for the conventional pressure and jointly endorsed by several expert committees [43,44], e.g. 140/90 and 160/95 mmHg, are also uniformly applicable to men and women and across all ages. Moreover, age is a much stronger correlate of the conventional than of the ambulatory blood pressure (Figure 1) [9].

The present thresholds (Table 1) are higher than those proposed by the Pamela investigators [13,14,16],

Table 1. Suggested operational thresholds for ambulatory blood pressure monitoring

	Normotension[a]	95% percentiles[b]	Hypertension[c]
24-h pressure (mmHg)	<130/80	133/81	≥135/85
Daytime pressure (mmHg)	<135/85	139/87	≥140/90
Night-time pressure	<120/70	124/74	≥125/75

[a]Obtained by rounding down to the next blood pressure value ending in 0 or 5.
[b]The averaged 95% percentiles in the normotensive subjects ($n=5048$) enrolled in the Belgian [10,11,15] and Japanese [7,17] population studies, in the International Database [5,18], and in the Allied Irish Bank Study [2] (for details, see reference [15]).
[c]Obtained by rounding up to the next blood pressure value ending in 0 or 5.

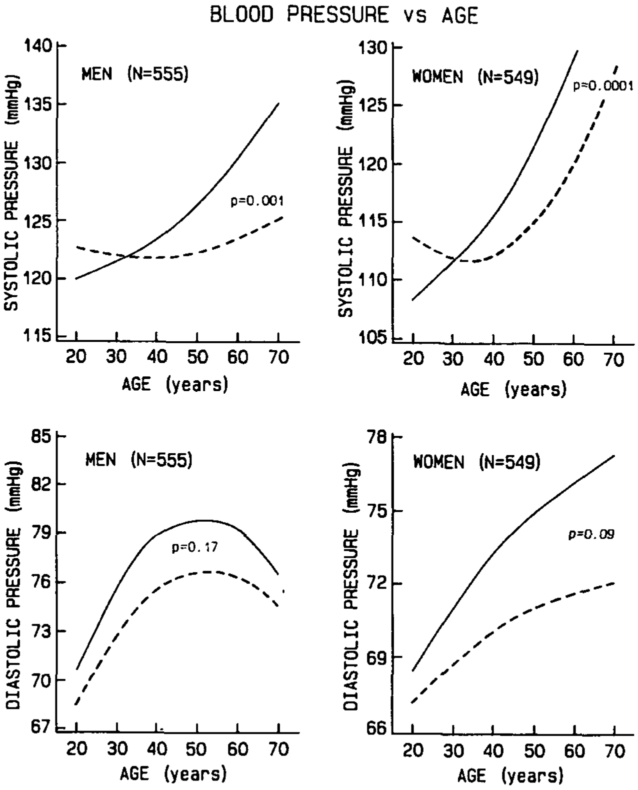

Fig. 1. The relationship between systolic (upper panels) and diastolic (lower panels) blood pressure and age in men (left panels) and women (right panels). The regression lines are shown for conventional (solid lines) and ambulatory (dashed lines) blood pressure measurements. The *P* values refer to the comparison of the regression lines (linear and quadratic slopes combined). From Staessen *et al.* [9], with permission.

who concluded that the upper limits of a normal 24-h ambulatory pressure would probably range from 120 to 130 mmHg for systolic pressure and from 75 to 81 mmHg for diastolic pressure (Ambulatory Blood Pressure, Satellite Symposium to the Seventh European Meeting on Hypertension, Milan, 1995). As in earlier studies [45], the latter thresholds were derived by regressing the 24-h pressures on the clinic pressures and by determining the 24-h values which would correspond with the generally accepted pressure limits used in clinical practice, i.e. 140 mmHg systolic and 90 mmHg diastolic [43,44]. However, the 95% confidence intervals about the regression lines from which the Pamela investigators [13,14,16] derived the upper limits of normality for the 24-h ambulatory pressures were those for the prediction of population means. Such intervals were determined in various strata according to gender and age. These confidence bands were then juxtaposed in order to obtain the overall interval of upper normal limits. As demonstrated in the Belgian study [15], the 95% confidence intervals for the prediction of the 24-h ambulatory pressures in individual subjects, i.e. the scatter of the individual 24-h values that can be expected at a clinic pressure of 140/90 mmHg, were obviously much wider than 120–130 mmHg systolic and 75–81 mmHg diastolic. Moreover, in the Pamela Study (Ambulatory Blood Pressure, Satellite Symposium to the Seventh European Meeting on Hypertension, Milan, 1995) normotensive subjects and untreated hypertensive patients were pooled in the regression analysis. Because the white coat phenomenon may be substantial in the latter, but less so in the former, it remains to be demonstrated that in these two subgroups the regression lines between the 24-h and the clinic pressures were coincident and that normotensive and hypertensive subjects could be reasonably pooled in the regression analysis.

The presently defined operational thresholds (Table 1) are to some extent supported by the prospective study by Verdecchia *et al.* [27]. Indeed, the proposed boundaries for the daytime pressures approximate to the cut-off values of 136/87 mmHg in men and 131/86 mmHg in women, below which Verdecchia demonstrated that the incidence of cardiovascular events was the same in white coat hypertensive and normotensive subjects [27]. Moreover, Devereux *et al.* [46] contrasted the ambulatory measurements in normotensive subjects with normal left ventricular geometry with those in patients with concentric left ventricular hypertrophy, the morphological pattern associated with the worst prognosis [22]. These investigators suggested that in adult men and women awake ambulatory blood pressures below 139/86 mmHg may be considered normal, whereas values over 145/95 mmHg should be viewed as pathological [46]. Along similar lines, Gosse *et al.* [47] found that the left ventricular mass index increased with higher daytime pressures, but not with a larger white coat effect defined as the difference between the clinic and the daytime pressure. In Gosse's study left ventricular mass index was on average not increased (125 g/m^2) in the patients belonging to the bottom quartile of the daytime pressures, in whom during the day systolic pressure ranged up to 133 mmHg and diastolic pressure up to 89 mmHg.

Whether the 24-h pressures, as opposed to either the daytime or night-time averages, are more meaningful from a clinical point of view, remains a focus of debate. The 24-h pressures incorporate the largest number of readings and are therefore more reproducible. A recent meta-analysis [48] demonstrated that left ventricular mass (index), in contrast to the prevailing opinion, was on average not more closely related to the night-time than to the daytime blood pressure. The 95% confidence intervals about the pooled correlation coefficients, representing the averages of up to 19 studies, ranged from 0.39 to 0.48 for the systolic night-time pressure and from 0.44 to 0.52 for the systolic daytime pressure ($P>0.2$ for the difference between day and night). For the diastolic pressures the point estimates of the pooled correlation coefficients were the same for the day and the night ($r=0.37$). The pooled correlation coefficients were, however, significantly stronger for the systolic (0.49 versus 0.46; $P<0.005$), but not diastolic (0.40 versus 0.38), 24-h pressures than for the corresponding daytime pressures. Thus, for now, the 24-h pressures should probably be viewed as the most informative.

Another practical consideration relevant to any proposal of a reference frame for ambulatory monitoring, relates to the proportion of subjects in whom the diagnosis of hypertension would be imposed or refuted, when in addition to conventional sphygmomanometry, ambulatory monitoring would also be employed to ascertain the diagnosis. In the International Database (Figure 2) [5] 7.9% of the normotensive subjects ($n=4577$) had a 24-h systolic pressure in excess of 130 mmHg, but only 3.4% had a 24-h systolic pressure higher than 135 mmHg; among the hypertensive patients with a conventional systolic pressure of at least 160 mmHg ($n=1324$), 17.7% had a 24-h systolic pressure of 130 mmHg or less, and 28.1% had a 24-h systolic pressure of 135 mmHg or less. Considering the presently proposed boundaries for the 24-h diastolic pressure (Table 1), 8.5 and 2.3% of the normotensive subjects had a 24-h diastolic pressure exceeding 80 and 85 mmHg respectively, whereas 22.6 and 40.5% of the hypertensive patients with a conventional diastolic pressure of at least 95 mmHg ($n=1310$), had a 24-h diastolic pressure below these limits. Thus in fewer than 10% of the subjects currently diagnosed as normotensive on the basis of conventional sphygmomanometry, the possibility of hypertension would have to be envisaged as a consequence of ambulatory monitoring. On the other hand as many as 20–40% of the hypertensive patients may have to be reclassified as normotensive after ambulatory monitoring. The latter observation is in keeping with previous reports in the literature [35, 49].

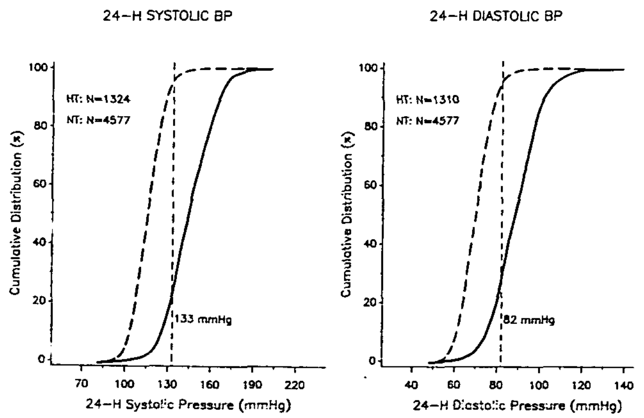

Fig. 2. The cumulative distributions of the 24-h systolic (left panel) and diastolic (right panel) blood pressures in normotensive (N; $n=4577$) and hypertensive (H; systolic $n=1324$; diastolic $n=1310$) subjects. The dotted vertical lines indicate the 95th percentiles in normotensive subjects. Approximately 30% of the hypertensive patients had a 24-h ambulatory blood pressure below these thresholds. From Staessen *et al.* [18], with permission.

Conclusions

Preliminary cut-off points for ambulatory monitoring may be derived by averaging the 95th percentiles of the ambulatory measurements in the normotensive subjects enrolled in various large-scale studies [2,5,10,11,18]. Although subjects normotensive on conventional sphygmomanometry, in the absence of other risk factors, do have a low cardiovascular risk profile in comparison with their hypertensive counterparts [38,39], the boundaries for ambulatory monitoring derived in this way need further validation in terms of the incidence of cardiovascular complications [30–34].

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