Systolic vs Diastolic Blood Pressure Control in the Hypertensive Patients of the PAMELA Population

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Background: Previous studies have shown that in the treated fraction of the hypertensive population, blood pressure (BP) control is less common for systolic BP (SBP) than for diastolic BP (DBP) as measured in the physician's office. Whether this phenomenon is artifactually attributable to a temporary increase in BP owing to a “white-coat” effect or represents a true rarity of SBP control in daily life is unknown.

Methods: Data were obtained from the PAMELA (Pressioni Arteriose Monitorate E Loro Associazioni) study population, which involved individuals ranging in age from 25 to 74 years who were representative of the residents of Monza (a city near Milan, Italy) and who were stratified according to sex. Office (an average of 3 sphygmomanometric measurements), home (an average of morning and evening self-measurements using a semi-automatic device), and 24-hour ambulatory (average of measurements performed every 20 minutes during the day and at night) BP values were obtained in all study subjects. In the treated hypertensive patients, BP was regarded as controlled if office values were less than 140 (SBP) or 90 (DBP) mm Hg. Home and 24-hour average SBP and DBP were regarded as controlled if the values were lower than 132/83 and 125/79 mm Hg, respectively.

Results: In the study participants (n = 2051), the number of patients with hypertension who were receiving antihypertensive treatment was 398, or approximately 42% of all individuals with hypertension. In-office SBP control by treatment was less frequent than DBP control (29.9% vs 41.5%, P < .05). This was also the case when home and 24-hour SBP and DBP control was considered (38.3% vs 54.6% and 50.8 vs 64.9%, respectively, P < .05 for both).

Conclusions: In the PAMELA population, SBP control by treatment was much less frequent than DBP control by treatment. This was the case not only for office BP values but also for home and 24-hour BP values, demonstrating that inadequate SBP control is not limited to artificial BP-measuring methods but occurs in daily life.

Arch Intern Med. 2002;162:582-586

SeVERAL STUDIES performed in a variety of countries have shown that blood pressure (BP) values are satisfactorily controlled by treatment in only a small fraction of the hypertensive population.1-9 Some of these studies have also shown that control by treatment is even less common for systolic BP (SBP) than for diastolic BP (DBP); ie, that in a number of patients, DBP values are lower than 90 mm Hg, while SBP values remain above 140 mm Hg.10-12 This finding has important adverse implications for public health, because in the general population SBP has been shown to be an equal or even more important cardiovascular risk factor than DBP.13,14 Furthermore, in elderly individuals with hypertension, a reduction in SBP by treatment has often been shown to be a more important determinant of a patient’s protection from cardiovascular disease than a reduction in DBP.15

We previously showed that a noticeable number of patients with hypertension in an urban population living in a town (Monza) northeast of Milan, Italy, were untreated and that among those who were treated only a small percentage had office BP values that were lower than 140/90 mm Hg, as has been documented in other countries.16 Herein we report the results obtained by analyzing the status of SBP control vs DBP control by treatment in the hypertensive fraction of the same population. This analysis provided data on SBP and DBP control based not only on office values but also on home and ambulatory BP values, which enabled us to determine the degree of SBP and DBP control in conditions of daily life.

RESULTS

In the PAMELA population, the percentage of subjects with an increase in office
SUBJECTS AND METHODS

The data reported herein originate from the PAMELA (Presioni Arteriose Monitorate E Loro Associazioni) study, which was performed to gather information on the normal values of ambulatory and home BP in a representative sample of the population of Monza, a town in the northeast district of Milan, Italy. The methodological aspects of the PAMELA study have been reported elsewhere. Briefly, 3200 individuals aged 25 to 74 years were selected from the Monza residents according to the age (decades), sex, and socioeconomic criteria of the World Health Organization’s MONICA (Monitoring Trends and Determinants in Cardiovascular Disease) Project, which was performed in the same geographical area. The individuals selected were asked by letter to report to the local hospital on a workday morning (Monday–Friday). The participants were interviewed and visited so that demographic data could be recorded and information on medical history, lifestyle, cardiovascular risk factors, and diseases could be obtained. The same information was obtained from nonparticipants who were interviewed by telephone and found to be similar to the participants in age, sex, socioeconomic status, and prevalence of cardiovascular risk and diseases. A trained physician measured the participants’ sitting BP 3 times using a mercury sphygmomanometer. The sitting BP was further measured (1) over 24 hours with an oscillometric device (model 90207; SpaceLabs Inc, Redmond, Wash) that was programmed to start the monitoring period after completion of the office BP measurements and to automatically read BP every 20 minutes and (2) in the morning and in the evening at home with a semiautomatic oscillometric device (model HP 5331; Philips, Tokyo, Japan) whose cuff had to be positioned on the arm contralateral to that used for ambulatory BP monitoring. The participants had to record the values shown on the digital display of the device in a diary and give it to the investigator. A similar number of subjects were studied during the 4 different seasons and during the 5 different weekdays.

For each participant, the 3 clinic BP values and the 2 home BP values were averaged, with the SBP and DBP values being averaged separately. Ambulatory SBP and DBP values were edited from artifacts and averaged over the 24 hours. There were 2051 participants in the study (64.1% of the overall sample). Home BP values were available for 1867 subjects. Ambulatory BP data were available for 2027 subjects and were found to be adequate (at least 70% of the 72 readings over the 24 hours were valid) in 96% of the subjects. In the group as a whole, the valid SBP and DBP readings were 94.7%±2.4% (mean±SD) and 93.5%±2.2%, respectively, of the 72 readings during the 24-hour period.

The subjects with hypertension were classified as unaware or untreated if (1) the office BP value was greater than or equal to 140 mm Hg systolic and/or 90 mm Hg diastolic, (2) the home BP value was greater than or equal to 132 mm Hg systolic and/or 83 mm Hg diastolic, and (3) the 24-hour average BP value was greater than or equal to 125 mm Hg systolic and/or 79 mm Hg diastolic with no history of antihypertensive drug treatment in the preceding 15 days. Selection of the home and ambulatory BP values was based on previous calculation of the upper limit of normal of the home and 24-hour average BP values for the whole PAMELA population. The subjects with hypertension were classified as treated, regardless of the BP values, if current antihypertensive drug treatment was reported. They were further classified as treated with SBP and DBP control if the report of current antihypertensive treatment was accompanied by an office SBP value of less than 140 mm Hg and an office DBP of less than 90 mm Hg, respectively. The SBP or DBP control was also established by home (systolic, <132 mm Hg; diastolic, <83 mm Hg) and 24-hour average (systolic, <125 mm Hg; diastolic, <79 mm Hg) BP values. Antihypertensive treatment was reported to consist of the use of a diuretic (23%), a β-blocker (8%), a calcium antagonist (9%), an angiotensin-converting enzyme inhibitor (18%), or a combination of 2 drugs or other treatments (42%).

Data were also analyzed in a similar fashion for groups of different age ranges (25-49, 50-64, and 65-74 years) and for men and women. Mean±SD values from the various groups were compared by 2-way analysis of variance using the t test for unpaired observations and the Bonferroni correction for multiple comparisons to locate between-group differences. A P value of .05 was taken as the level of statistical significance.

BP values who were unaware of their status or untreated was 26.6% of the overall number of subjects in whom office measurements were available. The corresponding figures for home and 24-hour BP values were 22.1% and 22.1%, respectively.

The number of subjects with hypertension who were treated was 398. As shown in Figure 1, (1) office SBP and DBP values were controlled in only 21.1% of the cases and (2) SBP control was less frequent than DBP control. Although the percentages were somewhat greater (Figure 1), similar findings were observed when SBP and DBP control was based on home and 24-hour BP values. This observation is further illustrated in Figure 2 which shows individual office, home, and 24-hour BP values in the treated subjects with hypertension. Figure 3 and Figure 4 show the data separately for sex and age. For office, home, and 24-hour BP values, systolic control was invariably less frequent than diastolic control in both men and women (Figure 3). Office, home, and 24-hour SBP control became progressively less frequent as age increased (Figure 4), whereas DBP control did not show any age-related change.

COMMENT

The PAMELA study has shown that in subjects who were identified as hypertensive by screening a large sample of an urban population living in the northeast district of Milan, BP control by treatment is rare. It has also shown that this is the case not only for office values but also for home and ambulatory values; therefore, this phenomenon is attributable not to a “white-coat” effect causing a temporary increase in BP but to a true rarity of BP control in daily life. The present analysis of the PAMELA data adds 2 pieces of evidence to these results: (1) the rare BP control of the treated hypertensive subjects of the
PAMELA population is more commonly attributable to an inadequate reduction of SBP than of DBP; (2) once again, the rare BP control involves not only office values but home and ambulatory BP values as well. Therefore, we may conclude that in the hypertensive fraction of the PAMELA population (1) an effective decrease in SBP is unquestionably less common than an effective reduction of DBP and (2) this also occurs when BP is measured at home or in ambulatory conditions, thus indicating that SBP control is indeed less common than DBP control in daily life.16

Our data are in line with the results of previous studies that have also observed a less frequent SBP than DBP control in treated patients with hypertension, although data were based only on office BP values.10-12 Therefore, it is important to discuss 2 possible explanations for a phenomenon that mainly accounts for the poor rate of overall BP control that has consistently been reported in various populations. One explanation is that current hypertensive drugs are less effective in lowering SBP than DBP, because the alteration involved in an SBP elevation, ie, an increase in arterial stiffness,23 is less easily reversible than the alteration that is involved in a DBP elevation, ie, an increase in arteriolar resistance to blood flow.23 The second explanation is that physicians titrate antihypertensive treatment of DBP and terminate further therapeutic efforts once DBP values are lower than 90 mm Hg, even when SBP values are higher than 140 mm Hg. It should

![Figure 1. The white part of the circles represents the percentage of treated hypertensive subjects in the PAMELA (Pressioni Arteriose Monitorate E Loro Associazioni) population with both systolic (S) and diastolic (D) blood pressure (BP) control, SBP control only, and DBP control only. The shaded part of the circle represents the percentage of treated hypertensive subjects with uncontrolled SBP and DBP, SBP only, or DBP only. Control was defined based on upper limits of office BP values (S, $\geq$140 mm Hg; D, $\geq$90 mm Hg), home BP (S, $\geq$132 mm Hg; D, $\geq$83 mm Hg) or 24-hour average BP values (S, $\geq$125 mm Hg; D, $\geq$79 mm Hg). The upper limits of home and 24-hour average BP values were derived from previous analysis of the data from the entire population. There were 398 treated hypertensive subjects, 339 and 390 of whom also underwent monitoring of home and 24-hour average BP values, respectively.](image1)

![Figure 2. Individual systolic (S) and diastolic (D) blood pressure (BP) values in all treated hypertensive subjects of the PAMELA (Pressioni Arteriose Monitorate E Loro Associazioni) study. The horizontal and vertical lines indicate the upper normal limits for office, home, and 24-hour SBP and DBP values.](image2)

![Figure 3. Percentage of treated hypertensive men and women (HTs) with systolic (S) or diastolic (D) blood pressure (BP) control based on office, home, or 24-hour values.](image3)
be emphasized that both these explanations may be valid, because large-scale studies of isolated systolic hypertension have shown that drug treatment based on SBP reduction rarely lowers SBP values below 140 mm Hg.\textsuperscript{24,25} Furthermore, in the large number of patients with systolic-diastolic hypertension who were recruited for the Hypertension Optimal Treatment (HOT) study,\textsuperscript{27} a reduction of DBP well below 90 mm Hg (average value, 83 mm Hg) was achieved, even when the SBP remained above 140 mm Hg. This finding was also noted among the hypertensive patients in the International Nifedipine GITS (gastrointestinal therapeutic system) Study: Intervention as a Goal in Hypertension Treatment (INSIGHT) study, in which the average DBP value was reduced by treatment to 82 mm Hg, while the SBP value remained only slightly below 140 mm Hg.\textsuperscript{28} This finding suggests that DBP control may be achieved at smaller doses and/or with a lesser number of drugs than SBP control, which may require more aggressive drug treatment.

Several other points deserve to be mentioned. First, in the PAMELA study office, home and ambulatory SBP control was less frequent than DBP control in both treated men and treated women. By and large, however, BP control was more frequent in women than in men. This outcome confirms and extends the results of previous studies that were based only on office BP values,\textsuperscript{10-12} which have suggested this phenomenon to be attributable not to a sex difference in the efficacy of antihypertensive drugs but to a greater compliance by women to antihypertensive treatment. Second, in the PAMELA study patients, the percentage of treated subjects with SBP control was progressively less from the youngest to the oldest age stratum, regardless of whether office, home, or ambulatory BP was considered. This result is unlikely to be accounted for by the fact that the compliance of elderly patients to treatment is less than that of younger patients, because DBP control was similar at all ages. It is more likely to depend on the fact that (1) physicians may adopt a less aggressive therapeutic attitude when they face a BP increase in the elderly (because of lack of full perception of its risk and/or fear of a “J curve” phenomenon) and (2) in the elderly the BP increase is more frequently systolic, i.e., the component of the BP profile that may be more difficult to normalize, possibly because of the limited reversibility of an increase in arterial stiffness. Third, in the treated hypertensive patients of the PAMELA population, SBP and DBP were more frequently found to be controlled when home or ambulatory rather than office BP normalization was considered, despite the very stringent criteria adopted to define the normal values for home and ambulatory BP.\textsuperscript{17} This result may depend on the fact that in some patients office BP may appear not to be normalized by treatment because of the temporary increase in BP values that is caused by a white-coat effect.\textsuperscript{22} Thus, when the prevalence of uncontrolled hypertension in a population is being investigated, office BP measurements may be complemented by BP measurements obtained outside the office to avoid an overestimation as a result of this phenomenon.

The very low frequency of SBP control in the hypertensive population has an obvious adverse significance for public health. Because SBP is now recognized as being an equal or even more important cardiovascular risk factor than DBP,\textsuperscript{13,14} its more common lack of control means that the population in general will remain at a high risk for cardiovascular complications. Furthermore, a more common reduction in DBP values than in SBP values induces an increase in pulse pressure, i.e., an increase in a variable that has recently been shown to be a possible independent risk factor for cardiovascular disease.\textsuperscript{29}

Accepted for publication July 17, 2001.

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