Longitudinal Study on Hypertension Control in Primary Care: The Insubria Study

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Background: Hypertension control is still unsatisfactory. The study was aimed to evaluate blood pressure (BP) control rate and the impact of training general practitioners (GPs) about hypertension 1999 World Health Organization/International Society of Hypertension guidelines.

Methods: After a training session on the hypertension guidelines, 588 GPs consecutively enrolled 5524 known hypertensive patients. During the first and follow-up visits (after 3, 6, and 9 months) GPs recorded BP, lifestyle habits, and drug therapy.

Results: The BP was controlled in 33.4%, with systolic BP less controlled than diastolic BP. The BP control rate decreased ($P < .001$) from low to very high cardiovascular risk group and from lean to overweight and obese subjects. At the first visit 97.3% of the patients were already on drug treatment: 40.3% with 1 drug, 38.9% with 2 drugs, 17.2% with 3 drugs and 3.6% with 4 or 5 drugs. The adherence to correct dietary and lifestyle habits was low. The drugs most often used were the angiotensin-converting enzyme inhibitors (3009 patients, 56%). During follow-up body weight and BP decreased; 1 or more drugs were added in 17.8% and the adherence to healthier lifestyle habits significantly increased. At the end of the survey BP control rate was significantly improved (52.7%).

Conclusions: In primary care the hypertension control rate was still unsatisfactory, and our data suggest that it may be due to a not aggressive enough drug treatment and a low adherence to recommended lifestyle and dietary habits. Increasing the knowledge of GPs about guidelines was associated with an improvement of hypertension control rate. Am J Hypertens 2006;19:140–145 © 2006 American Journal of Hypertension, Ltd.

Key Words: Blood pressure control, primary care, guidelines.

Hypertension is the most common treatable risk factor for cardiovascular (CV) diseases.1 Many studies have demonstrated that hypertension treatment decreases CV morbidity and mortality.2 Nevertheless, the rate of hypertension control is still far from satisfactory; less than one-third of hypertensive patients actually reaches the blood pressure (BP) goal.3–9 Therefore, the recently released hypertension guidelines underline the need for improving hypertension control rate, mostly in patients at high CV risk.7,10

Control rate of hypertension has been evaluated mainly at outpatient hypertension clinics or through large-scale population-based surveys, often with data obtained from retrospective analysis of medical records or from patients' self-reported BP and therapies.5,11–14 Some studies have been carried out in primary care, with a direct assessment of patients' BP and treatment by general practitioners (GPs).15,16 Among the main determinants of the unsatisfactory BP control there are physicians' behaviors, such as acceptance of less than optimal BP levels, discomfort in titrating therapy to the goal, lack of familiarity with guidelines, and, therefore, insufficient translation into everyday clinical practice.7,9 However, as far as we know, no longitudinal study has evaluated the impact of training GPs about guidelines on the rate of BP control.

As a result we designed a prospective study aimed to evaluate, in a primary care setting, the rate of BP control among known essential hypertensive patients and the impact of GP training about hypertension guidelines. The study was performed in the district of Varese, in northern Italy, between January and December 2000.

Methods

The Department of Clinical Governance asked all the 670 GPs working in the district of Varese to take part in the study and 588 GPs (87.8%) agreed to participate. They attended a 1-day training session on the 1999 World...
Health Organization/International Society of Hypertension (WHO/ISH) guidelines for the management of hypertension.\textsuperscript{17} All the aspects of hypertension diagnosis and treatment were presented, emphasizing on the evaluation of patients’ CV risk level, the different BP goals (general hypertensive population BP <140/90 mm Hg, diabetes mellitus, or kidney disease <130/85 mm Hg), the therapeutic relevance of lifestyle changes and weight reduction, also reinforcing the need of multiple drug therapy to reach the BP goal. The enrollment of patients started a few days after the training session. Each GP enrolled 5 to 10 consecutive patients (based on the number of subjects followed by the GP) with known essential hypertension (clinic BP ≥140 and/or 90 mmHg or current use of antihypertensive drugs). Secondary hypertension was ruled out by the GPs on the basis of clinical examination, blood tests, and instrumental examinations. This evaluation was done when high BP values were first diagnosed, before the enrollment into the study.

Each GP had to enrol the first known essential hypertensive patient who entered his office on Monday and Thursday, enrolling the second patient if the first refused to participate. Therefore, the GPs were not allowed to choose among their hypertensive patients which ones to enroll.

During the first visit, in addition to age, gender, and body mass index (BMI), the GP recorded, on the basis of clinical history and available examination, duration of hypertension, CV risk factors, target organ damage, associated CV disease, and drug therapy. Body weight and height were measured in a standardized manner. The BP was evaluated by the physician, averaging the values obtained with three measurements, taken by mercury sphygmomanometer, in the sitting position, at 5-min intervals. No standardized criteria were established for the assessment of target organ damage, which was defined by reports provided by the referring GP.

The degree of CV risk was established according to the 1999 WHO/ISH guidelines.\textsuperscript{17}

Each patient underwent three follow-up visits (after 3, 6, and 9 months) all performed by the GP. During each visit BP (as during the first visit), body weight and therapeutic changes were recorded and an interview was conducted about weekly frequency of physical activity (jogging, biking, exercise) and about dietary salt intake (salt added during cooking, weekly servings of ham and cheese that are both rich in sodium).

Hypertension control was defined as BP <140/90 mm Hg for the general hypertensive population, BP <130/85 mm Hg for patients with diabetes mellitus or kidney disease.\textsuperscript{17}

The study was approved by the Ethical Committee of the Department of Clinical Governance of the district of Varese and all the patients gave their informed consent.

### Statistical Analysis

The statistical analysis was carried out using analysis of variance for comparison of mean values among groups, analysis of variance for repeated measures for evaluation of longitudinal changes within each group, and \( \chi^2 \) test for comparison of proportions. The relationships of BP control with CV risk categories, age, gender, BMI, risk factors, and associated diseases were analyzed using multiple logistic regression. The statistical analysis was performed using the SPSS 11.5 software (SPSS Inc., Chicago, IL). A \( P \) value of < .05 (two-sided) was considered statistically significant.

### Results

A total of 5524 patients were enrolled. Demographic data are presented in Table 1. The prevalence of risk factors, target organ damage, and associated diseases is summarized in Table 2. The CV risk was low in 403 patients (7.3%), intermediate in 2138 (38.7%), high in 1329 (24.1%), and very high in 1654 (29.9%).

### First Evaluation

Systolic BP was controlled in 2009 patients (36.4%) and diastolic BP in 3825 patients (69.2%); both systolic and diastolic diastolic BP in 3825 patients (69.2%); both systolic and diastolic BP in 3825 patients (69.2%); both systolic and diastolic BP in 3825 patients (69.2%); both systolic and diastolic BP in 3825 patients (69.2%); both systolic and diastolic.
diastolic BP was controlled in 1845 patients (33.4%). The BP control rate was significantly lower in subjects aged 60 years or older (32.3%) than in younger subjects (38%), but the BP control rate was not significantly different between men (33.4%) and women (33.5%). Subdividing the patients on the basis of target organ damage or associated diseases, BP control was significantly worse in patients with kidney disease (14.8%) and diabetes (9.4%) (Table 3).

The BP control rate significantly decreased ($P < .001$) from the group with low CV risk (51.6%) to intermediate CV risk (38.5%), to high (27.2%) and very high CV risk (27.1%). This result held true also after adjustment for age. The BP control rate decreased significantly ($P < .001$) from lean patients (39.2%) to overweight (32.6%) to obese patients (26.8%). From the multivariate analysis, the main variable linked to poor BP control was the CV risk category ($P < .001$), followed by diabetes ($P < .005$), BMI ($P < .01$), renal dysfunction ($P < .01$), and age ($P < .02$).

Almost all the patients (97.3%) were already on antihypertensive treatment: 40.3% with 1 drug, 38.9% with 2 drugs, 17.2% with 3 drugs, and 3.6% with 4 or 5 drugs. The mean number of drugs used was 1.68 in low CV risk group, 1.62 in intermediate risk group, 1.85 in high risk group, and 2.08 in very high risk group ($P < .02$ the other CV risk groups). The drugs most often used were angiotensin-converting enzyme inhibitors (41.5% of patients treated with 1 drug, and 65.7% of patients treated with ≥2 drugs), followed by thiazides diuretics (1.5% of patients treated with 1 drug and 28.6% of patients treated with ≥2 drugs), calcium antagonists (28.6% of patients treated with 1 drug and 12.7% of patients treated with ≥2 drugs), β-blockers (12.7% of patients treated with 1 drug and 27.3% of patients treated with ≥2 drugs), and angiotensin II receptor blockers (ARBs) (10.6% of patients treated with 1 drug and 4.2% of patients treated with ≥2 drugs).

With regard to dietary and lifestyle habits, 44% of the patients usually added salt during cooking and ate cheese or ham more than three times a week; 43% of the patients were engaged in regular physical activity.

### Table 3. BP control at baseline in patients with diabetes mellitus, target organ damage, and associated diseases

<table>
<thead>
<tr>
<th>Variables</th>
<th>BP &lt;140/90 mm Hg</th>
<th>BP &lt;130/85 mm Hg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes, n (%)</td>
<td>253 (30.3)</td>
<td>73 (9.4)</td>
</tr>
<tr>
<td>Left ventricular hypertrophy, n (%)</td>
<td>395 (27.1)</td>
<td>197 (33.3)</td>
</tr>
<tr>
<td>Coronary artery disease, n (%)</td>
<td>59 (31.2)</td>
<td>28 (14.8)</td>
</tr>
<tr>
<td>Renal disease, n (%)</td>
<td>54 (29.3)</td>
<td></td>
</tr>
<tr>
<td>Heart failure, n (%)</td>
<td>141 (38)</td>
<td></td>
</tr>
<tr>
<td>Cerebrovascular disease, n (%)</td>
<td>70 (26.9)</td>
<td></td>
</tr>
<tr>
<td>Peripheral artery disease, n (%)</td>
<td>153 (27.8)</td>
<td></td>
</tr>
</tbody>
</table>

### Follow-up Visits

Only 63 patients (1.14%) were lost to follow-up (refusal to continue the study, 23 subjects; change of address, 14 subjects; death, 6 cerebrovascular disease, 4 myocardial infarction, 16 death other than CV).

During the follow-up body weight decreased, with mean BMI at the end of the study significantly reduced (from 27.1 ± 4.2 to 26.7 ± 4.1 kg/m², $P < .001$). The BP decreased from the first to the fourth visit (Fig. 1). At the end of the survey BP control rate was significantly ($P < .001$) improved. Systolic and diastolic BP were both controlled in 52.7% of the patients, with systolic BP controlled in 53.6% and diastolic BP controlled in 90.5% of the patients. The improvement in BP control rate held true subdividing the patients on the basis of CV risk. In each CV risk group control rate was significantly higher than at the first evaluation; however, control rate was still significantly ($P < .001$) lower in the high and very high CV risk groups than in the low and intermediate CV risk groups (Fig. 2). The same trend was found considering the three groups of lean, overweight, and obese patients. The BP control rate increased in each group, but it was still significantly ($P < .001$) lower in obese (43.5%) than in overweight (52.4%), than in lean hypertensives (59.1%).

During the follow-up one or more drugs were added to the previous treatment in 17.8% of the patients. Drug treatment was increased in 19.6% of the patients who reached BP control and in 15.8% of the patients who did not reach BP control ($P = .003$); thiazide diuretics were the most frequently added drugs. Less than 1% of the subjects had one drug withdrawn from the treatment regimen. Considering lifestyle habits, at the end of the study the number of patients adding salt during cooking, eating ham or cheese more than three times a week was significantly decreased (from 44% to 28%, $P < .001$). There was also a significant increase of patients engaged in regular physical activity (from 43% to 50%, $P = .001$).

### Discussion

The rate of hypertension control has been evaluated following different approaches: recruitment of patients in
hypertension units, large-scale community surveys, studies in primary care setting. Our study is an example of the primary care setting, with the GPs recording the patients' clinical history and treatment and directly measuring body weight and BP. The Varese’s Department of Clinical Governance invited all of the GPs to take part in the study with a response rate of 87.8%, and the physicians enrolled the patients consecutively, with the only inclusion criterion of known essential hypertension. This avoided a “pre-selection,” which could have led to the participation of only the GPs more interested in hypertension or to the enrolment of “better controlled” or “more difficult” hypertensive patients. Another relevant characteristic of our study is the method chosen for BP evaluation. Instead of one BP measurement and a single threshold of $140/90$ mm Hg to define controlled BP as used in most of the previous surveys, the BP was measured three times during each visit and we used different cutoff values for the general hypertensive population ($<140/90$ mm Hg) and for hypertensive patients with diabetes or kidney disease ($<130/85$ mm Hg), as indicated by the 1999 guidelines. These methods allow a more reliable evaluation of actual BP values and of BP control rate.

The BP was controlled in 33.4% of the patients, a low control rate, especially considering that all the patients were known to be hypertensive. Our BP control rate is similar to the one found in Belgium (38%, with different target BP values) and significantly higher than the control rate (18.7%, with target BP $<140/90$ mm Hg) found in Germany. A comprehensive review of data mainly derived from population registries showed that, on average, in European countries BP is controlled (BP $<140/90$ mm Hg) in the general hypertensive population in less than 10% of subjects, whereas in treated hypertensives the
control rate changed from 40.3% in England to 18.7% in Spain, with a value of 28.1% in Italy. This control rate is lower than in our study, more so considering that we used two different cutoff BP values, a method that leads to a control rate lower than that obtained using the 140/90 mm Hg threshold for all the patients. Our BP control rate was higher than the rate from community surveys, which is probably due to the high number of BP readings, the more recent evaluation (BP control tends to improve over time), and the higher percentage of subjects already on antihypertensive therapy.

Systolic BP was less controlled than diastolic BP, in agreement with other studies, especially in older hypertensive patients, despite the major role of systolic BP as an independent CV risk factor. Many characteristics of the patients, such as age, gender, stage of hypertension, degree of CV risk, are considered predictors of BP control. With the exception of a lack of difference in control rate between men and women, our results are in agreement with the literature. In fact, subjects older than 60 years had a worse BP control than younger subjects and, as in other studies, BP control decreased from low to high and very high CV risk categories. The 1999 guidelines did not include BMI in the evaluation of CV risk. However, taking into account the role of obesity as a CV risk factor, we compared the BP control rate in lean, overweight, and obese patients. Hypertension control was significantly worse in overweight and obese subjects.

These results are probably due to a lack of aggressive enough antihypertensive treatment, mainly in high risk patients. Recent data show that over-reliance on monotherapy is one of the most important factors responsible for the persistently low rates of hypertension control. Almost all of our patients (97.3%) were already on antihypertensive treatment, with a mean number of drugs ranging from 1.62 in the intermediate CV risk group to 2.08 in the very high CV risk group. Only 20% of the patients were treated with three or more drugs, despite that 54% were patients at high or very high CV risk, therefore requiring three to four drugs or even more to achieve BP control, as demonstrated by clinical trials. This findings, together with the low hypertension control rate, indicate that antihypertensive therapy was too weak in most patients. Comparing our results with those from other countries, our prevalence of multiple drug treatment (59.7%) was slightly different, being higher in comparison with the Belgian study (46%) and lower than the prevalence found in Spain (63.7%).

The angiotensin-converting enzyme inhibitors were the drugs most often prescribed, alone as well as in combination, followed by thiazide diuretics and calcium antagonists. These latter were used in monotherapy as well as in combination therapy, whereas diuretics were administered almost always in combination with other drugs and only in very few patients as monotherapy. When the study was performed in Italy, ARBs could only be prescribed to patients who developed cough with angiotensin-converting enzyme inhibitors and this explain the very low rate of ARBs use in our patients. Our results are in agreement with the findings from Spain. In Belgium, β-blockers, calcium antagonists, and diuretics were the drugs most often used. Taken together these results indicate an attitude toward different therapeutic strategies, in agreement with the latest European guidelines.

The results about dietary and lifestyle habits indicate that the majority of these known hypertensive patients were eating too much salt and was not engaged in any regular physical activity. Therefore, the adherence to nonpharmacologic antihypertensive treatment was low, as demonstrated also by the great number of overweight or obese subjects.

Recent studies documented that physicians are often willing to accept BP values higher than the guideline BP goals, as a result of an antihypertensive treatment perceived as “effective.” The second aim of our study was to evaluate the impact of a brief training session on hypertension guidelines on patients’ treatment. During the follow-up there was a decrease in BP and body weight, with an improvement in BP control, which was significant in all groups. However, it has to be underlined that the differences found at the first visit among the groups still persisted, with a worse control in high and very high risk groups and in obese subjects. Looking for an explanation of the improved BP control we verified that during the follow-up one or more drugs were added in 17.8% of the patients, and, as a consequence of training, GPs paid a greater attention to reinforcing healthier lifestyle habits, leading more patients to reduce salt intake and to increase physical activity.

Our study has some limitations. To keep the study protocol as simple as possible, we did not established standardized criteria for the assessment of target organ damage (ie, left ventricular hypertrophy), which was defined on the basis of reports of previously performed analyses (electrocardiogram or echocardiogram for left ventricular hypertrophy). This leads to a variability of diagnostic criteria and therefore the CV risk stratification may not have been always correct. A second problem is the lack of a control group of GPs who did not undergo the training. Because of this lack of a comparison group we cannot establish a causal relationship between the training and the improvement in hypertension control rate.

In conclusion, our results demonstrate that in primary care the rate of hypertension control is still largely unsatisfactory and this is likely to be due to a “weak” antihypertensive drug treatment and a low adherence to healthy lifestyle and dietary habits. Moreover, the rate of BP control is worse in hypertensives at higher CV risk, who could benefit the most from an effective BP control. However, increasing the knowledge of GPs about hypertension guidelines appears to be associated with an improvement in hypertension control rate, which is probably mainly related to a more aggressive drug treatment and a greater
attention to the reinforcement of correct dietary and lifestyle habits, a very cost-effective intervention. Primary care is the most important setting to reach BP control and maximum benefit in terms of CV risk reduction, therefore strategies are needed to increase the familiarity of GPs with clinical guidelines, making easier to apply in everyday clinical practice.

References


