

## Blood pressure and lipid goal attainment in the hypertensive population in the primary care setting in Spain

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### Abstract

Although blood pressure (BP) control is crucial in hypertensive patients, clinical practice guidelines agree that the goal of treatment should be aimed at not only decreasing BP but reducing global cardiovascular risk. The aim of this cross-sectional study was to evaluate BP, low-density lipoprotein cholesterol (LDL-C), and composite control rates in a hypertensive population in a primary care setting in Spain. Good BP control was defined as <140/90 mm Hg (<130/80 mm Hg for diabetics). LDL-C control rate was established according to the third report of the National Cholesterol Education Program Adult Treatment Panel criteria. A total of 12,954 patients (49.9% women, aged 62.1±10.7 years) were included. BP was controlled in 24.8% of patients, LDL-C in 26% of patients and, when combined, in only 8.6%. The rates of control were significantly worse in high-risk subgroups, such as high-coronary-risk, diabetic, or metabolic syndrome patients. The BP and LDL-C control rates in the hypertensive population attended to daily in primary care settings in Spain are low.

Hypertension is one of the main cardiovascular (CV) risk factors. Different guidelines have shown that the presence of hypertension increases CV morbidity and mortality. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7)<sup>1</sup> and the European guidelines for the management of arterial hypertension<sup>2</sup> show that even small elevations above optimal blood pressure (BP) values increase the likelihood of developing a CV disease. In 1990, MacMahon and colleagues<sup>3</sup> demonstrated that BP lowering is critical in reducing the risk of CV outcomes and preventing major coronary events. Nevertheless, although BP control is crucial, clinical practice guidelines agree that the aim of treatment in hypertensive patients should not only be to control BP but to reduce CV risk. Thus, a multifactorial intervention appears to be critical in improving CV prognosis in hypertensive patients.<sup>2</sup>

In the United States, the third report of the National Cholesterol Education Program Adult Treatment Panel (NCEP ATP III)<sup>4</sup> establishes low-density lipoprotein cholesterol (LDL-C) level control as a main objective for the primary and secondary prevention of coronary disease. It is well known that the prevalence of hypercholesterolemia is higher in the hypertensive population and vice versa.<sup>5,6</sup> Treatment of multiple risk factors may improve CV risk in hypertensive patients. Clinical trials, such as the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT),<sup>7-9</sup> have demonstrated that the integration of a multifactorial approach reduces the risk of CV morbidity and mortality.

Nevertheless, epidemiologic studies often analyze different CV risk factors independently. The Prevención Cardiovascular en España en Atención Primaria: Intervención Sobre el Colesterol en Hipertensión (PRESCOT) study is a cross-sectional trial designed to determine not only the BP control but also the LDL-C and the composite of BP and LDL-C control rates in the hypertensive population treated in a primary care setting. In addition, the BP, LDL-C level, and the composite control rates in high-risk patient subgroups, such as patients with high coronary risk, diabetes, or the metabolic syndrome (MetS), are determined.

Preliminary data of this study were presented at the 20th Annual Scientific Meeting of the American Society of Hypertension in San Francisco, CA, May 14–18, 2005.

## Patients and methods

### *Study Population*

The study population involved patients with hypertension included in the PRESCOT cross-sectional epidemiologic survey. The study was aimed to determine the BP, LDL-C, and composite control rates in a population of patients with hypertension attending general practice clinics across Spain daily. Approximately 2000 primary care physicians participated in the study, which was performed during 2004. Each investigator was asked to include the first 6 consecutive outpatients with hypertension who were seen at the clinic. Men and women older than 18 years who had an established diagnosis of hypertension and an available blood test with a complete lipid profile performed within the past 6 months were included in the study. To correctly reflect the clinical daily practice, no specific exclusion criteria were defined.

### *Methodology and Data Collection*

BP readings were taken with mercury sphygmomanometers or validated automatic devices where available, after 5 minutes of rest. The patient was in a seated position with the back supported. Two measurements were taken, and the mean was recorded. BP was considered to be well controlled according to the 2003 European Society of Hypertension/European Society of Cardiology (ESH/ESC) guideline recommendations (<140/90 mm Hg for the general population and <130/80 mm Hg for diabetic patients).<sup>2</sup> Patients were classified as being at low, medium, or high coronary risk according to the NCEP ATP III classification.<sup>4</sup> We used NCEP ATP III guidelines because of their utility in identifying coronary risk in clinical practice and their definition of LDL-C goals. LDL-C control was thus defined in relation to the above risk categories: LDL-C <100 mg/dL for the high-risk group, <130 mg/dL for the medium-risk group, and <160 mg/dL for the low-risk group.<sup>4</sup>

MetS was diagnosed using NCEP ATP III criteria requiring the presence of 3 or more of the following factors: abdominal obesity (waist circumference >102/88 cm or >40/35 inches for men/women); triglyceride level  $\geq$ 150 mg/dL; high-density lipoprotein cholesterol level <40/50 mg/dL (men/women); fasting glucose level  $\geq$ 110 mg/dL; or BP  $\geq$ 130/85 mm Hg.<sup>4</sup> Waist circumference was measured at the midpoint between the iliac crest and the costal margin. Smoking was defined as current smokers of  $\geq$ 1 cigarette per day and exsmokers who had stopped smoking for more than 12 months. Excessive alcohol intake was classified as a weekly consumption of the equivalent of 26 oz of 40-proof alcohol. Sedentary lifestyle was defined as the physical activity undergone in a period shorter than a 30-minute daily walk, and renal failure by a serum creatinine level >1.5 mg/dL in men and >1.4 mg/dL in women, according to European guidelines.<sup>2</sup> The presence of diabetes was recorded from the clinical history. The diagnosis of left ventricular hypertrophy was reported by the investigator either by electrocardiography or echocardiography. The physicians fulfilled a specific individual case report form with all of the collected clinical and analytic data for every patient.

### **Statistical analyses**

Various statistical tests were performed depending on the nature of the variables being compared. The chi-square test was used to analyze the relationship between categorical variables. When more than 20% of the cells had an expected frequency of lower than 5, however, the Fisher exact test was used. Comparison of continuous variables between groups was performed using the Student *t*-test. Database recording was subjected to internal consistency rules and ranges to control inconsistencies/inaccuracies in the collection and tabulation of data (SPSS version 11.0.1; SPSS Inc, Chicago, IL).

### **Results**

The PRESCOT survey enrolled a total of 15,707 patients of whom 12,954 (82.5%) were included in the analysis after excluding those who did not comply with the selection criteria and/or whose case report forms were incomplete and/or inconsistent. Table I details the baseline characteristics of the overall study population. Mean age was  $62.1 \pm 10.7$  years and 49.9% were women. Body mass index was  $28.5 \pm 4.1$  kg/m<sup>2</sup> and waist circumference was  $99.3 \pm 16.0$  cm ( $101.8 \pm 14.3$  cm in men and  $96.9 \pm 17.1$  in women). Mean BP values were  $144.1 \pm 14.2/85 \pm 9.1$  mm Hg. The time of evolution of hypertension was  $6.7 \pm 5.4$  years. A total of 76% of the patients had dyslipidaemia, 52% had MetS, and 29.9% had diabetes. The

most frequent target organ damage was left ventricular hypertrophy (11.9%) and the most frequent associated clinical condition was coronary artery disease (13.6%).

**Table I.** Characteristics of the PRESCOT Study Population (N=12,954)

Demographic data	
Women	6468 (49.9)
Age, y	62.1±10.7
Body mass index, kg/m <sup>2</sup>	Men: 28.4±3.6 Women: 28.5±4.6
Waist circumference, cm	Men: 101.8±14.3 Women: 96.9±17.1
Cardiovascular risk factors	
Dyslipidemia	9850 (76.0)
Diabetes	3868 (29.9)
Smoking	4875 (37.6)
Family history of premature coronary disease	4209 (32.5)
Vascular disease	
Heart disease	4164 (32.1)
Left ventricular hypertrophy	1539 (11.9)
Coronary disease	1765 (13.6)
Heart failure	591 (4.6)
Renal impairment	1358 (10.5)
Microalbuminuria	851 (6.6)
Proteinuria	143 (1.1)
Renal failure, serum creatinine*	351 (2.7)
Stroke	699 (5.4)
Peripheral arterial disease	566 (4.4)
Clinical data	
SBP, mm Hg	144.1±14.2
DBP, mm Hg	85.0±9.1
Biochemical data	
Total cholesterol, mg/dL	233.1±41.8
Triglycerides, mg/dL	158.1±80.0
LDL cholesterol, mg/dL	150.9±92.8
HDL cholesterol, mg/dL	53.3±18.1
Fasting plasma glucose, mg/dL	110.5±32.0
Uric acid, mg/dL	5.4±1.9

Values are mean ± SD or No. (%). \*For men, serum creatinine values >1.5 mg/dL and for women, 1.4 mg/dL. PRESCOT indicates Prevención Cardiovascular en España en Atención Primaria: Intervención Sobre el Colesterol en Hipertensión; SBP, systolic blood pressure; DBP, diastolic blood pressure; LDL, low-density lipoprotein; and HDL, high-density lipoprotein.

Most patients (94.5%) were taking at least 1 drug, but 5.5% of patients were not receiving pharmacologic treatment. More than half (55.9%) of the patients with antihypertensive medication were on monotherapy, and 38.6% were treated with 2 or more drugs. The most frequently prescribed antihypertensive agents were the angiotensin-converting enzyme inhibitors and the more common combination was a diuretic with an inhibitor of the renin-angiotensin system. Despite 76% of the patients being dyslipidemic, only 41% were treated with lipid-lowering agents, with statins being the most frequently prescribed.

BP was controlled in 24.8% of patients. Systolic BP was controlled in 28.5% of patients, while diastolic BP was controlled in 50.9%. The LDL-C control rate was 26%. The degree of control of combined BP and LDL-C was very low (8.6%). Overall study population BP and LDL-C control data are presented in the Figure. Predictive factors of uncontrolled BP were diabetes, renal impairment, excessive alcohol intake, sedentary lifestyle, and left ventricular hypertrophy ( $P<.05$ ), and those for lack of LDL-C

control were diabetes, the presence of associated clinical conditions, uncontrolled BP, excessive alcohol intake, overweight, sedentary lifestyle, and absence of lipid-lowering treatment ( $P<.05$ ). Table II and Table III show the odds ratios and confidence intervals of the predictive factors for uncontrolled BP or LDL-C.

**Table II. Predictive Factors for Lack of BP Control ( $P<.05$ )**

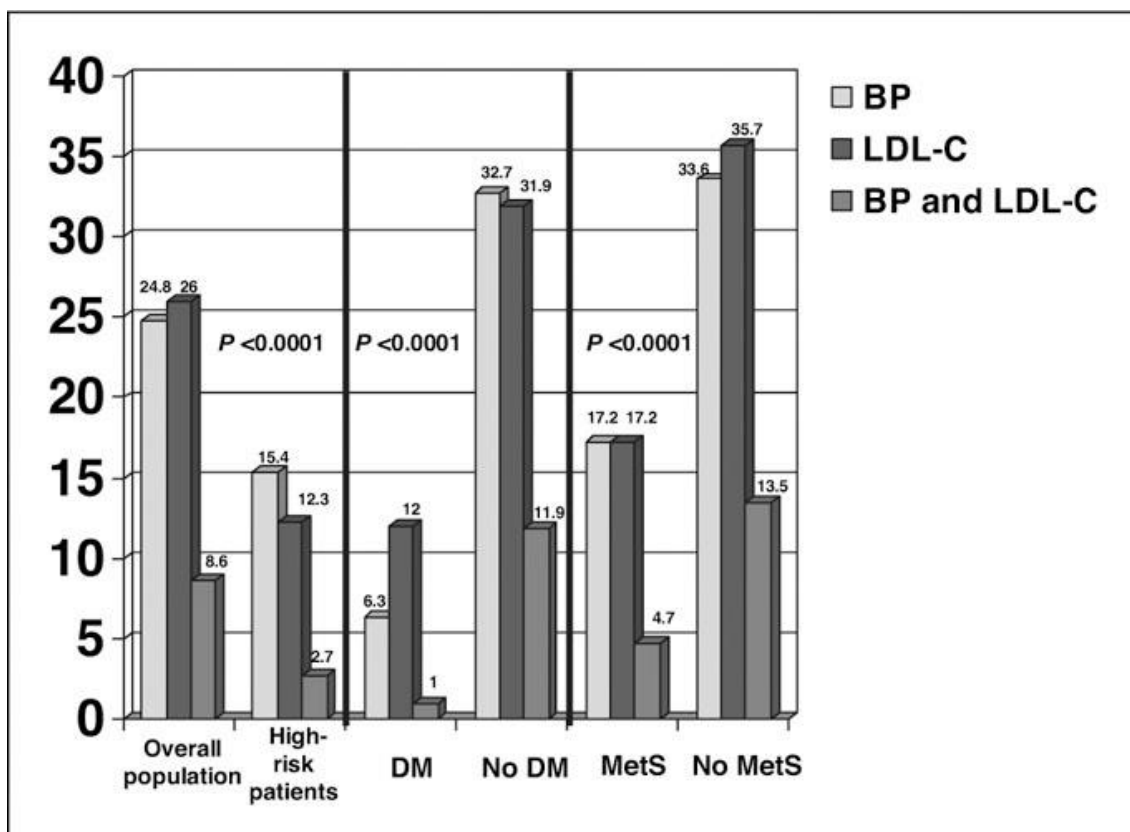
Predictive Factors	Odds Ratio	95% Confidence Interval
Diabetes	6.37	5.51–7.37
Renal impairment	2.77	2.16–3.55
Excessive alcohol intake	1.41	1.27–1.56
Sedentary lifestyle	1.35	1.23–1.47
Left ventricular hypertrophy	1.23	1.06–1.42

**Table III. Predictive Factors for Lack of Low-Density Lipoprotein Cholesterol Control ( $P<.05$ )**

Predictive Factors	Odds Ratio	95% Confidence Interval
Diabetes	3.13	2.77–3.55
Associated clinical conditions*	1.74	1.56–1.95
No blood pressure control	1.54	1.40–1.71
Excessive alcohol intake	1.35	1.19–1.52
Overweight (25–30 kg/m <sup>2</sup> )	1.21	1.08–1.37
Sedentary lifestyle	1.16	1.05–1.27
Lipid-lowering agents treatment	0.79	0.72–0.87

\*Includes stroke, peripheral arterial disease, coronary disease, and heart failure.

The control rates in high-risk subgroups (patients with high coronary risk, diabetes, or MetS) were lower than the comparators (for all,  $P<.0001$ ) (Figure). BP was well controlled in 37.5% of the low-risk subgroup, in 30.2% of the medium-risk group, and in 15.4% of the high-risk subgroup. LDL-C control was 65.6% in the low-risk group, 28% in the medium-risk group, and 12.3% in the high-risk group. Only 25.8% of the patients at low risk had both controlled BP and LDL-C, whereas 9.6% of medium-risk patients and 2.7% of high-risk group had controlled BP and LDL-C.



Blood pressure (BP), low-density lipoprotein cholesterol (LDL-C), and combined control rates according to coronary risk and the presence of diabetes mellitus (DM) and the metabolic syndrome (MetS).

BP was controlled in fewer patients in the subgroup of MetS compared with those without MetS (17.2% vs 33.6%;  $P < .0001$ ). Systolic BP was controlled in 20.7% of MetS patients and in 37.2% of non-MetS patients ( $P < .0001$ ), while diastolic BP was controlled in 39.0% vs 63.7% ( $P < .0001$ ), respectively. Similarly, LDL-C control was worse in MetS patients than in patients without MetS (17.2% vs 35.7%;  $P < .0001$ ). The combined control of both risk factors was also lower in patients with the MetS (4.7% vs 13.5%;  $P < .0001$ ).

In diabetics, BP control ( $< 130/80$  mm Hg) and LDL-C control ( $< 100$  mg/dL) were lower than in patients without diabetes (6.3% vs 32.7% [ $P < .001$ ] and 12% vs 31.9% [ $P < .001$ ]). In only 1.0% of the patients with diabetes, both parameters were properly controlled (vs 11.9% of patients without diabetes;  $P < .001$ ). When considering BP control  $< 140/90$  mm Hg, 22.9% of diabetics vs 32.7% of nondiabetics attained goal ( $P < .001$ ).

## Discussion

In the past few years, a number of pivotal studies on the early detection and BP control treatment of hypertension have been performed. These studies have shown a progressive improvement in the rates of BP control lately.<sup>10-12</sup> Nevertheless, surveys reveal that in more than 50% of patients treated for hypertension, it is not yet controlled.<sup>13,14</sup> As evidence shows, the aim of treatment in hypertensive patients should not only be to control BP values but mainly to reduce CV risk.<sup>2</sup> Although recent guidelines emphasize the concomitant management of multiple CV risk factors, few studies have assessed treatment patterns and combined BP and LDL-C goal attainment in the hypertensive population.<sup>15-17</sup> Our results show that BP and LDL-C control rates are globally low but are even worse in high-risk patients, such as patients with diabetes or MetS, or those classified as being at high coronary risk according to NCEP ATP III guidelines. Several studies have shown similar results.<sup>5,15-20</sup> Despite the fact that the Mediterranean population seems to exhibit a low CV risk when compared with those in other Western countries,<sup>21</sup> most patients who are treated in primary care clinics in Spain are actually at medium or high coronary risk.<sup>5,20</sup>

Therefore, it is critical to identify the associated risk factors and to take a global multifactorial therapeutic approach to improve the prognosis of hypertensive patients.

Regarding BP control rates, our data show that only 24.8% of patients achieve BP goals. Several studies have shown poor BP control in the primary care setting.<sup>10–12,22</sup> Our data are consistent with these studies; however, this situation does not only occur in primary care but also in hospital hypertension units, as the CLUE study<sup>23</sup> demonstrated. A number of factors may be involved in this lack of BP control in clinical practice, including the underestimation of real risk, the scarce importance given to systolic BP, poor treatment adherence, and therapeutic inertia.<sup>5,10,24,25</sup> Clinical inertia implies that physicians do not usually make changes even though BP is not controlled.<sup>26</sup> Our study shows that despite the fact that primary care hypertensive patients who attend an outpatient clinic daily present a high coronary risk, only 56% of them are taking antihypertensive monotherapy. This low proportion of combined therapy may play a role in the low BP control rates. Moreover, in high-risk patients it is more difficult to achieve BP goals. As an example, while BP control is considered to be <140/90 mm Hg in diabetics, the control rates were higher in nondiabetics.

Several studies have been aimed at determining lipid control. These studies showed very low LDL-C control rates in high-coronary-risk patients in primary care.<sup>27–29</sup> In the same way, poor goal attainment was observed in the Lipid Treatment Assessment Project (L-TAP),<sup>30</sup> in which only 40% of dyslipidemic patients receiving statin monotherapy reached their LDL-C goals. Moreover, this situation does not improve in hospitalized patients.<sup>31,32</sup> Our results are consistent with these data. Despite that 76% of the study population had dyslipidemia and that LDL-C control rates were low, only 41% were treated with lipid-lowering agents. This situation is even worse in patients with diabetes, MetS, or high coronary risk.

Our results showed that diabetes was the main predictor of the lack of BP and LDL-C control. Of interest, the absence of BP control is a predictive factor of no LDL-C control, which emphasizes the relationship between BP and hypercholesterolemia and the importance of globally treating the patient.<sup>6</sup> In the hypertensive population, it is critical to control not only BP but other CV risk factors as well. A recent study showed that less than half of all treated patients reach the therapeutic goal for either BP or LDL-C.<sup>16</sup> Researchers observed that very few patients with concomitant hypertension and dyslipidemia, especially among those patients with diabetes, attained their therapeutic goals for both BP and LDL-C. Similarly, our data showed that in high-risk patients, both parameters are often poorly controlled, which may imply relevant clinical consequences. The ASCOT trial is a clear example of how the treatment of associated CV risk factors in hypertension results in a significant improvement of prognosis.<sup>9</sup> Therefore, patients with hypertension need to be treated with more antihypertensive combined therapy and statins. Antihypertensive treatment and lipid-lowering agents, however, are not the only important agents that should be used in the treatment of hypertensives. Our results show that despite that nearly one third of the overall population had heart disease, fewer than a quarter of patients received antiplatelet therapy. Therefore, a global approach is warranted to improve CV prognosis in hypertensive patients and even more in high-risk subgroups.

The cross-sectional design of the study was chosen to represent the “real world” of clinical practice as best as possible. Consequently, a large population of hypertensive patients was included in the trial by consecutive sampling. This methodology has limitations because it reduces the level of control that can be exercised to reduce variation and bias (eg, random sampling and blind controls). The large number of patients included and the nature of the end points being measured, however, with no comparators under review, minimizes this theoretic limitation. In fact, the study was designed to represent clinical practice, presenting an accurate picture of the hypertensive population who were managed daily in primary care.

In conclusion, the PRESCOT study is one of the very few studies performed in the primary care setting that analyzed both BP and LDL-C control rates in hypertensive patients. This study includes a large sample of patients who were seen daily by general practitioners and demonstrates that BP and LDL-C control rates are low and that there are few patients who have both risk factors adequately controlled. Notably, fewer than 9% of hypertensive patients have both parameters well controlled, and this is even worse in high-risk patients, which may result in significant clinical implications. This management of hypertensive patients through an aggressive multifactorial approach for reducing the CV risk in general practice requires improvement.

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