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ORIGINAL ARTICLE

Baseline Characteristics and Clinical Management of Patients Attended in Primary Care Setting According to the Presence of Cardiovascular Disease

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Abstract

Objective: To determine the clinical characteristics and management of patients according to the presence of Cardiovascular Disease (CVD) within a primary care setting.

Methods: IBERICAN is a longitudinal, observational, multicenter study that is currently including subjects aged 18 to 85 years attending primary care setting in Spain. The enrolled cohort will undergo an annual visit for at least 5 years. In this article, the baseline characteristics of the first 4,304 patients are reported.

Results: Compared with patients without CVD, those patients with CVD were older, more frequently men, and had more CV risk factors and target organ damage. Less than 60% of patients achieved blood pressure goals, < 10% LDL-cholesterol targets and 65% of diabetics HbA1c goals. More than 55% of patients had none or only one risk factor adequately controlled. CV risk factors control was independent of the presence of CVD. The CVD group showed higher use of prescribed drugs, but less than ideal.

Conclusions: Our study shows a poor level of CV risk factors control in the overall studied population. This observation was even more significant when applied to patients with established CVD. Our data strongly suggest the need for a more intense use of combined therapies in order to achieve an adequately control of CV risk factors within the Spanish primary care setting.

Keywords

Cardiovascular disease, Cardiovascular risk factors, Control, Diabetes, Dyslipidemia, Hypertension

Introduction

Cardiovascular Diseases (CVD) are the leading cause of mortality worldwide [1]. The genesis and progression of atherosclerosis and CVD is modulated by the presence of several of the so-called CV risk factors such as, hypertension, dyslipidemia, diabetes, smoking status,

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obesity, sedentary lifestyle, etc. In fact, the co-existence of several of these CV risk factors is used for the appropriated stratification of patients at risk for CVD. If untreated, CVD may even progress to target organ damage (i.e. microalbuminuria, left ventricular hypertrophy) and finally to end-stage vascular disease (i.e. ischemic heart disease, heart failure, stroke, or peripheral artery disease) [2].

Several studies have demonstrated that the control of the risk factors along the CV continuum significantly delays with the progression of CVD [2,3]. In this context, attaining the objectives recommended for the CV risk factors is essential to reduce the development of CV complications, particularly through a comprehensive therapeutic approach [4].

Many clinical trials have focused on analyzing CV risk factors control separately and their impact on CVD, particularly ischemic heart disease [5-7]. However, it would be of great interest to determine the incidence and adequate management of the of different CV risk factors in clinical practice on the entire CV continuum.

The aim of the IBERICAN (Identificación de la poBlaciónEspañola de RIesgoCArdiovascular y reNal) study was to determine the prevalence and incidence of diabetes, hypertension, dyslipidemia, smoking status and obesity, as well as the development of target organ damage and new or recurrent CV events in patients with or without known CVD attended in primary care setting in Spain [8]. The aim of this study was to analyze the baseline characteristics and clinical management of patients attended in primary care setting according to the presence of CVD.

Methods

IBERICAN is an ongoing epidemiological, observational, prospective and multicenter study. Patients aged 18 years or older, of both sexes, daily attending at primary care centers in Spain, regardless the presence of CV risk factors or CV disease, and that accept participating in the study, are being included. All patients will be followed-up every year at the primary care center with a minimum follow-up of 5 years. This study was approved by the Clinical Research Ethics Committee of the Hospital Universitario Clínico San Carlos of Madrid, Spain on 21 February 2013 (C.P. IBERICAN-C.I. 13/047-E) and endorsed by the Institutional Clinical Research Ethics Committees of each one of the recruiting Centers. The IBERICAN study has been registered at https://clinicaltrials.gov with the number NCT02261441 [8].

Each investigator was asked to include the first 10 consecutive subjects that met the following inclusion criteria: Patients of both sexes, aged between 18 and 85-years-old, users of the Spanish National Health Care System, living in Spain for the last 5 years and that gave written informed consent. Those patients who were planning to move to another city or country in the next 6 months, with a limited life expectancy in the following 5 years, or in whom it was expected to have problems with the follow-up were excluded from the study. Until 2 December 2016, a total of 4,304 patients have been recruited by 524 investigators throughout Spain [8].

At the baseline visit, data were collected from the medical history and physician interview. The data were entered in an electronic case report form specifically developed for the IBERICAN study. No study-specific diagnostic or therapeutic intervention was performed. Socio demographic data, CV risk factors, history of CV disease, physical examination (Blood Pressure [BP], heart rate, height, weight and waist circumference) as well as the number and type of treatments (antithrombotic, antihypertensive, lipid lowering and antidiabetic drugs) were recorded. In addition, data from the 12-lead electrocardiogram and blood and urine analyses performed in the previous 6 months when available according to clinical practice were also recorded [8].

CV risk factors (hypertension, dyslipidemia, diabetes, smoking status, obesity, abdominal obesity, sedentary life style), target organ damage (microalbuminuria, left ventricular hypertrophy, ankle brachial index < 0.9) and vascular disease (ischemic heart disease, heart failure, stroke, peripheral artery disease, and chronic kidney disease) were defined according to the 2013 European Society of Hypertension/European Society of Cardiology guidelines [9]. Metabolic syndrome was defined according to the International Diabetes Federation [10]. In this study, CVD was defined as the presence of ischemic heart disease, heart failure, stroke or peripheral artery disease.

Adequate BP control was defined according to the 2013 European Society of Hypertension/European Society of Cardiology guidelines (general population: BP < 140/90 mmHg; diabetics: BP < 140/85 mmHg; and patients ≥ 80 years: BP < 150/90 mmHg) [9]. Adequate LDL-cholesterol control was defined according to the 2016 European Guidelines on CV disease prevention in clinical practice (very high-risk patients: LDL-cholesterol < 70 mg/dL; high-risk patients: LDL-cholesterol < 100 mg/dL; low to moderate risk patients: < 115 mg/dL) [3]. A good diabetes control was defined as HbA1c < 7.0% [3].

Statistical Analysis

For the descriptive analysis, quantitative variables were described with measures of central tendency and dispersion (mean and standard deviation) and qualitative variables were described as absolute (n) and relative (%) frequencies. The Kolmogorov-Smirnov test was used to assess the normality distribution. In the bivariate analysis to compare 2 means, parametric (Student t test) or nonparametric (Mann-Whitney U test) statistical tests were performed based on the sample distribution. To compare percentages, the chi-square test or

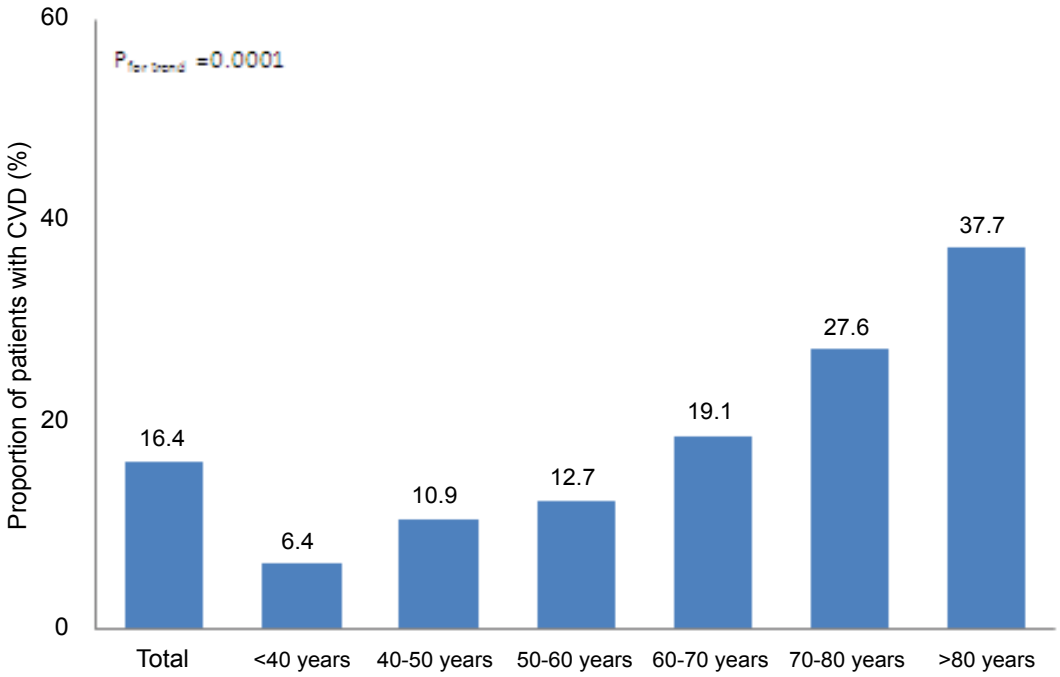

Figure 1: Proportion of patients with cardiovascular disease according to age.
CVD: Cardiovascular Disease.

Fisher test were used, according to the sample size. A logistic regression analysis was performed to identify those variables associated with CVD. Statistical significance was set at a P-value < 0.05. The statistical analysis was performed using IBM SPSS version 22.0.

Results

A total of 4,304 patients were included in the study, of whom 707 (16.4%) had CVD (ischemic heart disease, stroke, heart failure or peripheral artery disease). As shown in Figure 1, the proportion of patients with CVD markedly increased with age, from 6.4% in those patients < 40 years, to 37.7% in those subjects > 80 years.

The clinical characteristics of the patients according to the presence of CVD were analyzed (Table 1). Compared with those patients without CVD, subjects with CVD were older, more frequently men, and had more CV risk factors, target organ damage and vascular disease, including atrial fibrillation and chronic kidney disease. Time of evolution of hypertension (11.8 ± 6.9 vs. 9.6 ± 6.3 years; p = 0.0001), dyslipidemia (9.9 ± 6.1 vs. 8.2 ± 5.6 years; p = 0.0001) and diabetes (10.8 ± 6.5 vs. 9.6 ± 6.3 years; p = 0.015) was also higher in patients with CVD compared to patients without CVD.

Among those patients with atrial fibrillation, patients with CVD had a higher thrombo embolic risk ($CHADS_2 \geq 2$: 84.2% vs. 42.1%, respectively; p = 0.001; CHA_2DS_2-VASC ≥ 2: 96.8% vs. 69.9%, respectively: p = 0.0001) and a higher bleeding risk (HAS-BLED ≥ 3: 53.7% vs. 31.6%, respectively; p = 0.016). With regard to physical examination, whereas systolic BP, body mass index and waist circumference were significantly higher in those patients with CVD, heart rate was lower in patients with CVD (Table 1).

The biochemical parameters according to the presence of CVD were shown in Table 2. Whereas the fasting plasma glucose, triglycerides and creatinine levels were higher in CVD patients, total cholesterol, HDL-cholesterol, LDL-cholesterol and estimated glomerular filtration rate were higher in patients without CVD.

The number of antithrombotic, antihypertensive and lipid lowering drugs were significantly higher in patients with CVD compared to patients without CVD. Antidiabetic drugs were equally prescribed in both groups (Table 3). The most frequent antihypertensive drugs prescribed were angiotensin receptor blockers followed by diuretics in both groups. The most frequent lipid lowering drugs prescribed were statins followed by ezetimibe. With regard to anti diabetics, metformin followed by dipeptidyl peptidase 4 inhibitors were the commonest agents prescribed (Table 3).

At baseline, CV risk factors were equally controlled in patients with and without CVD. Less than 10% of patients achieved LDL-cholesterol targets in both groups. More than 55% of patients had none or only one CV risk factor adequately controlled, regardless the presence of CVD (Figure 2).

Predictors of CVD were shown in Table 4. CV risk factors, target organ damage, atrial fibrillation, chronic kidney disease and metabolic syndrome were independently associated with the presence of CVD.

Discussion

Current guidelines recommend systematic CV risk assessment in individuals at increased CV risk, such as those with major CV risk factors or comorbidities increasing CV risk as well as in men > 40 years of age and

Table 1: Clinical characteristics of the study population according to the presence of cardiovascular disease.

	Overall (n = 4, 304; 100%)	CV disease (n = 707; 16.4%)	No CV disease (n = 3,597; 83.6%)	P
Biodemographic data				
Mean age (years)	57.5 ± 13.5	64.1 ± 12.8	56.2 ± 14.5	0.0001
Gender, male (%)	45.1	54.3	43.2	0.0001
Habitat (%) Urban Semi-urban Rural	 52.9 26.0 21.1	 51.3 25.1 23.6	 53.2 26.2 20.6	 NS
Physical examination				
Systolic blood pressure (mmHg)	129.2 ± 15.7	131.5 ± 15.6	128.7 ± 15.8	0.0001
Diastolic blood pressure (mmHg)	76.6 ± 10.2	76.4 ± 10.3	76.7 ± 10.2	NS
Heart rate (bpm)	73.2 ± 10.5	72.5 ± 10.5	73.4 ± 10.5	0.043
Body mass index (Kg/m^2)	28.6 ± 5.1	29.7 ± 5.3	28.4 ± 5.1	0.0001
Waist circumference (cm)	96.1 ± 14.2	99.4 ± 14.4	95.5 ± 14.1	0.0001
Cardiovascular risk factors				
Dyslipidemia (%)	50.1	66.9	46.8	0.0001
Hypertension (%)	47.7	67.5	43.9	0.0001
Metabolic syndrome (%)	38.4	51.1	36.0	0.0001
Obesity (%)	34.6	41.9	33.2	0.0001
Abdominal obesity (%)	30.7	37.0	29.5	0.0001
Sedentary lifestyle (%)	30.6	34.8	29.8	0.011
Diabetes (%)	18.7	30.3	16.5	0.0001
Smoking status (%) Active smoker Never smoker Ex-smoker	 18.1 52.4 29.5	 15.8 48.2 36.0	 18.5 53.2 28.3	 0.0001
Family history of CV disease (%)	16.9	37.0	13.0	0.0001
Excessive alcohol intake (%)	13.0	14.5	12.7	NS
Organ damage				
Any target organ damage (%)	25.6	49.4	21.0	0.0001
Microalbuminuria (%)	8.0	15.7	6.5	0.0001
Left ventricular hypertrophy (%)	4.3	12.4	2.7	0.0001
Ankle brachial index < 0.9 (%)	2.0	12.4	0	0.0001
Vascular disease				
Chronic kidney disease (MDRD) (%)	9.5	16.2	8.2	0.0001
Ischemic heart disease (%)	7.3	44.7	0	0.0001
Stroke (%)	4.2	25.5	0	0.0001
Peripheral artery disease (%)	3.1	19.0	0	0.0001
Heart failure (%)	3.0	18.1	0	0.0001
Atrial fibrillation (%) $CHADS_2$ score CHA_2DS_2-VASC score HAS-BLED score	5.1 1.5 ± 1.0 2.6 ± 1.3 1.2 ± 0.8	15.6 2.8 ± 1.3 4.4 ± 1.5 1.6 ± 0.9	3.0 1.2 ± 0.9 2.3 ± 1.3 1.1 ± 0.8	0.0001 0.0001 0.0001 0.001

CV: Cardiovascular.

Table 2: Biochemical parameters according to the presence of cardiovascular disease.

	Overall	CV disease	No CV disease	P
Glucose (mg/dL)	101.8 ± 28.0	107.5 ± 29.6	100.7 ± 27.2	0.0001
HbA1c (%) in diabetics	7.0 ± 1.3	7.1 ± 1.5	7.0 ± 1.2	NS
Total cholesterol	196.4 ± 39.1	185.5 ± 42.6	198.5 ± 38.1	0.0001
HDL-cholesterol	54.9 ± 15.0	51.6 ± 14.1	55.5 ± 15.4	0.0001
LDL-cholesterol	118.2 ± 35.4	108.9 ± 38.3	120.0 ± 34.3	0.0001
Triglycerides	124.7 ± 86.5	135.7 ± 99.4	122.6 ± 82.3	0.0001
Creatinine (mg/dL)	0.87 ± 0.5	0.95 ± 0.5	0.85 ± 0.5	0.01
eGFR (MDRD)	86.1 ± 24.0	80.3 ± 23.3	88.1 ± 24.9	0.0001

CV: Cardiovascular; eGFR: estimated Glomerular Filtration Rate.

in women > 50 years of age or post-menopausal even without known CV risk factors [3]. Our study showed the significant impact of age on CVD, particularly among subjects aged 60 years or older. As a result, CV risk assessment should be performed in these individuals, or at least an active search for no known CV risk factors.

Table 3: Therapeutic approach according to the presence of cardiovascular disease.

	Overall	CV disease	No CV disease	P
Antithrombotic drugs				
Antiplatelets (%)	14.2	44.6	8.2	0.0001
Anticoagulants (%)	4.6	15.1	2.6	0.0001
VKA	4.1	13.6	2.3	0.0001
DOACs	0.5	1.5	0.3	0.0001
Nonsteroidal anti-inflammatory drugs (%)	12.7	11.7	12.9	NS
Antihypertensive drugs				
Number of antihypertensive drugs	1.7 ± 0.9	2.0 ± 1.0	1.6 ± 0.9	0.0001
Number of antihypertensive drugs 0 1 2 3 > 3	 6.3 40.2 34.7 15.7 3.1	 4.4 28.5 36.5 24.3 6.3	 6.7 42.5 34.3 14.0 2.5	 0.0001
ARB (%)	44.9	48.8	44.2	NS
Diuretics (%)	44.6	48.2	43.9	NS
ACEi (%)	36.6	32.3	37.5	0.044
Calcium channel blockers (%)	22.5	31.4	20.7	0.0001
Beta blockers (%)	18.3	33.8	13.1	0.0001
Alpha blockers (%)	3.5	4.4	3.2	NS
Lipid lowering drugs				
Number of lipid lowering drugs	0.7 ± 0.5	1.0 ± 0.5	0.7 ± 0.5	0.0001
Number of lipid lowering drugs 0 1 2 3	 27.8 66.9 5.2 0.1	 15.0 75.5 9.1 0.4	 30.3 65.3 4.4 0	 0.0001
Statins (%)	67.4	79.7	65.0	0.0001
Fibrates (%)	6.0	6.8	5.9	NS
Ezetimibe (%)	1.4	7.8	2.2	0.0001
Others (%)	0.8	0.6	0.8	NS
Antidiabetic drugs				
Number of antidiabetic drugs	1.6 ± 0.9	1.5 ± 0.9	1.6 ± 0.9	NS
Number of antidiabetic drugs 0 1 2 3 4	 10.3 41.1 33.8 12.2 2.6	 8.4 45.8 32.2 11.2 2.4	 10.7 40.2 34.1 12.4 2.6	 NS
Metformin	75.0	67.3	76.5	0.011
Dipeptidyl peptidase 4 inhibitors	30.4	31.8	30.2	NS
Insulin	20.7	29.0	19.1	0.004
Sulfonylureas	14.5	11.2	15.2	NS
Glinides	4.6	4.7	4.6	NS
Sodium-glucose Cotransporter-2 inhibitors	4.2	3.3	4.4	NS
GLP-1 receptor agonists	3.0	3.7	2.9	NS
Thiazolidinediones	2.6	2.3	2.6	NS

CV: Cardiovascular; VKA: Vitamin K Antagonists; DOACs: Direct Oral Anticoagulants; ARB: Angiotensin Receptor Blockers; ACEi: Angiotensin Converting Enzyme inhibitors.

Our study showed that compared with patients without CVD, those patients with CVD were older, and had a worse clinical profile. In addition, time of evolution of major CV risk factors (hypertension, dyslipidemia and diabetes) was longer in patients with CVD. As expected, CV risk factors and target organ damage were independent predictors for the development of CVD. Previous studies have shown a worse clinical profile in patients with CVD compared to those patients without CVD [11-15]. Importantly, in contrast to the majority of the studies in which the clinical profile of patients was analyzed according to the presence of only one type of CVD, our study analyzed CVD as a whole, providing a more comprehensive view of these patients.

Our study showed that CV risk factors were poorly controlled. In fact, more than 55% of patients had none or only one CV risk factor adequately controlled. Importantly, no significant differences were observed according to the presence of CVD. In the last years, a number of studies have analyzed the evolution of CV risk factors control rates according to the presence of CVD. Once

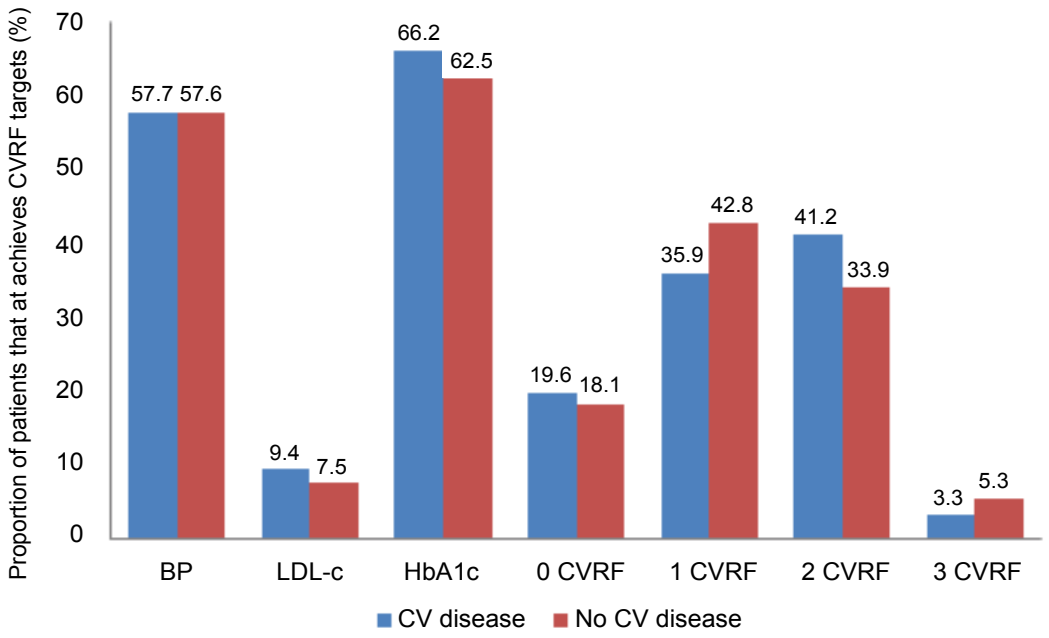

Figure 2: Cardiovascular risk factors control rates.

BP: Blood Pressure; LDL-C: LDL Cholesterol; CVRF: Cardiovascular Risk Factor. No significant differences were found between both groups in any of CVRF control rates.

Table 4: Predictors of cardiovascular disease.

Variable	Odds Ratio	95% confidence interval
Ankle brachial index < 0.9	6.80	6.33-7.30
Atrial fibrillation	5.95	4.50-7.87
Left ventricular hypertrophy	5.07	3.76-6.85
Any target organ damage	3.67	3.10-4.34
Microalbuminuria	2.69	2.11-3.42
Hypertension	2.65	2.23-3.14
Dyslipidemia	2.29	1.93-2.72
Diabetes	2.20	1.83-2.64
Chronic kidney disease	2.15	1.69-2.73
Metabolic syndrome	1.86	1.58-2.18
Gender, male	1.45	1.27-1.66
Obesity	1.45	1.22-1.71
Abdominal obesity	1.40	1.18-1.66
Sedentary lifestyle	1.25	1.06-1.48

again, the majority of these studies have been focused only in one type of CVD. EUROASPIRE IV was a cross-sectional study undertaken at 78 centers from 24 European countries in which patients < 80 years with coronary disease were included. In this study, 57.3% of patients achieved BP goals, 19.5% attained LDL-cholesterol targets and 54% of men with diabetes and 49% of women with diabetes reached a HbA1c < 7.0% [16]. In another study that compared two national registries of patients with chronic ischemic heart disease carried out in 2006 (n = 1,583) and 2014 (n = 1,110) in Spain, whereas BP control worsened (76.7% of patients achieved BP goals in 2006 vs. 66.3% in 2014; P < 0.01), LDL-cholesterol control (from 9.5% to 27.3%, respectively; P < 0.01) and glucose control in diabetics (from 13.8% to 20.2%, respectively; p = 0.01) improved [17]. In the ASPIRE-S study, 302 patients with prior ischaemic stroke were included. At 6 months post ischemic stroke, 63.4% of patients had a BP > 140/90, 23% LDL-cholesterol > 2.5 mmol/L and 28% of diabetic patients HbA1c ≥ 7% [18]. In a stroke-specific study module of the EUROASPIRE III survey in which 881 patients with first-ever ischaemic stroke from four European countries were included, only 37.6% and 24.3% of patients achieved BP and LDL-cholesterol goals, respectively [19]. Of note, different studies have shown that CV risk factors are better controlled in patients with coronary heart disease than in patients with prior stroke [20,21]. Among patients with peripheral artery disease, in a study that compared patients > 65 years with patients < 65 years, BP targets were achieved in 71.7 and 67.7% of patients, respectively, and LDL-cholesterol goals in 40.2 and 27.4%, respectively [22]. Data from the REACH registry showed that patients with peripheral artery disease did not achieve CV risk factors control as frequently as individuals with coronary artery disease or cerebrovascular disease [23]. All these data show that CV risk factors are poorly controlled in clinical practice, even in secondary prevention patients, in whom the risk of a new CV event is very high.

With regard to treatments, although the number of antithrombotic, antihypertensive and lipid lowering drugs were significantly higher in patients with CVD compared to patients without CVD, the majority of patients were not adequately controlled. For example, in nearly 40% of patients with CVD, no antithrombotic therapy was prescribed. Although this is less evident in patients with coronary artery disease, this has been described more frequently in other types of CVD [14-23].

In the last years, BP control rates have improved, and this may be related with the higher use of com-

bined therapy [24]. However, this increase seems insufficient. On the other hand, renin angiotensin system inhibitors were the most frequent antihypertensive drug prescribed in our study. This is in the line with current guidelines that recommend the use of these drugs as first-line therapy in patients with hypertension and CVD [9]. With regard to lipid lowering drugs, nearly 80% of patients with CVD were taking statins and 8% ezetimibe. Other studies have shown that although the prescription of statins is high, many patients with CVD are taking low or moderate intensity statins. In addition, combination with ezetimibe seems low [17]. However, it has been demonstrated that high intensity statins reduce CV complications when compared with moderate intensity statins, and that combining statins with ezetimibe may provide further beneficial effects [25,26]. Considering that the majority of patients with CVD do not achieve LDL-cholesterol targets, more efforts should be performed to increase the use of both, high intensity statins and combination of statins with ezetimibe. In our study, more than 60% of patients achieved HbA1c targets, but also more than 40% of patients were taking only one antidiabetic drug. Current guidelines recommend combining metformin with a second antidiabetic drug when HbA1c targets are not achieved with metformin alone [27]. This is even more important, considering that recent clinical trials have demonstrated that some new antidiabetic drugs may improve CV prognosis [28]. Therefore, combining drugs is mandatory to improve the adequate control of CV risk factors.

Our study has some limitations that should be considered. Although IBERICAN is a prospective study, only baseline data are presented here. As a result, this study has the inherent limitations associated with observational and retrospective studies. However, the high numbers of patients included and the meticulousness of the data recorded may limit this bias. In addition, this is the best design to show a picture of the current situation about CV risk factors control in “real-life” patients given the wide age range of the involved subjects. Thus, it should provide relevant data to illustrate the gaps between guidelines recommendations and clinical practice.

Conclusions

The presence of CVD markedly increased with age, particularly in subjects ≥ 60 years. Compared with patients without CVD, those patients with CVD were older, and had a worse clinical profile. The control of CV risk factors control was very far from optimal. In fact, more than 55% of patients had none or only one CV risk factor adequately controlled. CV risk factors control was independent of the presence of CVD. The prescription of antithrombotic drugs was low, particularly in patients with CVD. A more intensive use or higher use of combined therapy is required to improve CV risk factors control rates.

Learning Points

- Baseline characteristics and clinical management of patients attended in primary care setting in Spain according to the presence of CVD, including ischemic heart disease, heart failure, stroke and peripheral artery disease, were analyzed.
- CV risk factors and target organ damage were more frequent in patients with CVD than in patients without CVD.
- CV risk factors control rates were poor (< 60% of patients achieved BP goals, < 10% LDL-cholesterol targets and around 65% of diabetics HbA1c goals).
- CV risk factors control rates were similar among patients with CVD and those without CVD.
- The prescription of antithrombotic drugs was low, particularly in patients with CVD.
- A higher use of combined therapy is required to improve CV risk factors control rates.

Conflict of Interest

IBERICAN is promoted by SEMERGEN (Sociedad Española de Médicos de Atención Primaria). This study has been founded by SEMERGEN and with non-conditional grants of Astra Zeneca, Almirall, Menarini, Daiichi-Sankyo, La Caixa, Coca-Cola and Lacer. The authors have no relevant conflict of interest to disclose.

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