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Original article

Control of blood pressure in hypertensive patients on combination therapy☆

Alejandro de la Sierra[a,*], Anna Oliveras[b], Pedro Armario[c], Silvia Lucas[d], on behalf of the investigators of the COMBICONTROL study[◊]

[a] *Servicio de Medicina Interna, Hospital Mutua Terrassa, Universidad de Barcelona, Barcelona, Spain*
[b] *Servicio de Nefrología, Hospital del Mar, Barcelona, Spain*
[c] *Área de Enfermedades Cardiovasculares, Hospital Moisés Broggi, Sant Joan Despí, Barcelona, Spain*
[d] *Departamento Médico, Menarini, Barcelona, Spain*

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ABSTRACT

Background and aim: The impact of antihypertensive treatment on blood pressure (BP) control is fairly unknown. The aim of the study was to evaluate the degree of BP control and its relationship with treatment-related factors in hypertensive patients treated with two or three agents and attended in referral units.
Patients and methods: We studied 1337 hypertensive subjects (41% women) with a mean age (SD) of 63 (12) years, who were receiving two or three antihypertensive drugs. The degree of BP control was estimated in a single visit by the proportion of patients with BP below 140/90 mmHg.
Results: BP was controlled in 767 patients (57%). Lack of BP control was related to older age (12% risk for each 10-year increase) and the presence of microalbuminuria (64% risk increase). In those treated with two agents, BP control was 61%, without differences between those treated with fixed-drug or free combinations. BP control in those treated with three agents was 55%, higher in those receiving three agents in a fixed-drug combination (68%) compared with those on three agents administered separately (52%; $p = 0.025$). Drug classes used in combinations did not influence the degree of BP control.
Conclusions: The degree of BP control in patients treated with two or three agents is 57%. Microalbuminuria is related to a lack of BP control. In those receiving three agents, the use of fixed-drug combinations is associated with better BP control.

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Control de la presión arterial en pacientes en tratamiento con terapia combinada

Palabras clave:
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Control de la presión arterial
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Asociaciones farmacológicas

RESUMEN

Fundamento y objetivo: El impacto del tratamiento antihipertensivo sobre el control de la presión arterial (PA) es poco conocido. El objetivo del estudio ha sido examinar el grado de control de la PA y su relación con aspectos derivados del tratamiento en hipertensos tratados con 2 o 3 fármacos y atendidos en unidades hospitalarias.
Pacientes y método: Se han estudiado 1.337 hipertensos (41% mujeres) con una edad media (DE) de 63 (12) años, en tratamiento con 2 o 3 fármacos antihipertensivos. El grado de control se ha estimado en una única visita, calculando la proporción de pacientes con cifras inferiores a 140/90 mmHg.
Resultados: Un total de 767 pacientes (57%) tenían las cifras de PA controladas. El riesgo de mal control tensional se incrementaba con la edad (12% para cada 10 años) y con la presencia de oligoalbuminuria (64% de incremento). En los tratados con 2 fármacos, el grado de control fue del 61%, sin diferencias entre combinaciones fijas o libres. Los tratados con 3 fármacos presentaban tasas de control del 55%, mayores en

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* Corresponding author.
E-mail address: adelasierra@mutuaterrassa.es (A. de la Sierra).

◊ The names of the study COMBICONTROL investigators can be found in Annex 1.

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los que recibían una asociación fija de los 3 antihipertensivos (68%) frente a los 3 fármacos por separado (52%; p = 0,025). Los principios farmacológicos utilizados en las combinaciones no influyeron en el grado de control.

Conclusiones: El 57% de los pacientes en tratamiento con 2 o 3 antihipertensivos tiene sus cifras de presión controladas. La presencia de oligoalbuminuria se asocia al mal control. En los tratados con 3 fármacos, la utilización de asociaciones fijas se asocia con mayor control.

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Introduction

The main problem in the treatment of high blood pressure (HBP) is that a significant part of the treated population does not manage to keep their blood pressure (BP) figures below therapeutic objectives, frequently set at values lower than 140/90 mmHg.[1] Though cooperative data is scarce, heterogeneous, and not always contemporary, global figures seem to set BP control below 50%.[2]

In Spain, data on the progression of control is somewhat contradictory. Thus, studies conducted on both the general population randomly selected from the census[3–5] and patients from primary care consults,[6–9] seem to show some improvement regarding control rates, which would exceed 50%. However, studies conducted in reference units, where strict BP measurement is apparently more homogeneous, show certain stagnation, with 2 similar studies conducted 8 years apart that demonstrate a prevalence of 42% in both instances.[10,11] This tendency towards stagnation would match an independent review of most of the studies published in the last decade, which included hypertensive Spanish patients, but with heterogeneous characteristics.[12]

Some studies that have assessed BP control in the treated hypertensive population have outlined patient characteristics associated with poor BP control. Female sex, obesity, and the co-existence of other risk factors, such as smoking, dyslipidaemia or diabetes, are all factors associated with a greater resistance to treatment.[11,13] On the other hand, there is practically no evidence on the impact that treatment (in particular, the drugs used and their possible combinations) has on the control of BP figures. Though it is believed that inadequate therapeutic adherence, clinical inertia, and the poor use of pharmacological combinations may affect the lack of control,[14] there is no data as to whether the use of fixed or free combinations, as well as the kinds of drugs used in those combinations, may or may not have an impact on attaining control figures. In that regard, various international guidelines support the use of combinations that are considered preferential, though the heterogeneity of said recommendations is evident.[1,15–17]

In this study, we assessed the degree of control in a cohort of patients selected because they received an antihypertensive pharmacological treatment with 2 or 3 combined drugs. Our objectives were especially focused on the characteristics of said treatment (fixed or free combinations, as well as the kind of drugs used) and its impact on control. Likewise, we analysed the patient characteristics that correlated with the lack of blood pressure control.

Patients and method

Patient selection

This study involved 1,337 hypertensive male and female patients over the age of 18 who were selected consecutively in 2012 from 36 high blood pressure/vascular risk hospital units located in 12 autonomous communities in Spain. The inclusion criteria were the presence of HBP (defined by at least 3 separate measurements with figures equal to or higher than 140 and/or 90 mmHg), a minimum follow-up of 6 months conducted by the investigator or the pertinent unit and an antihypertensive pharmacological treatment consisting of 2 or 3 antihypertensive drugs in a fixed or free combination during a minimum of 3 months before data collection.

Design and method

The study was authorised by the clinical research ethics committees of the participating centres. Once informed consent was obtained, the patients' clinical data was collected from their previous medical history or by means of a direct questionnaire and clinical examination. The variables collected were age, gender, length of HBP, family history of premature cardiovascular disease, weight, size and body mass index calculation (obesity defined by a body mass index ≥30 kg/m^2), waist perimeter (abdominal obesity defined by values over 102 cm in male patients and 88 cm in female patients), smoking (active consumption of cigarettes or other tobacco products) and history of diabetes (blood sugar levels >125 mg/dL or treatment with antidiabetic drugs) or cardiovascular disease (coronary disease, cerebrovascular disease, heart failure, peripheral arterial disease and progressed retinopathy). BP was determined by means of a mercury sphygmomanometer or a validated electronic oscillometric device, according to the Spanish Society of Hypertension[1] recommendations. We also recorded antihypertensive treatment (number of drugs) as well as the pharmacological substances used and combination type (fixed or free, in patients with a 2-drug treatment; fixed, free or mixed, the latter being defined as a 2-drug fixed combination and a third separate drug, in patients with a 3-drug treatment). Basic blood test data was collected and the presence of renal disease was assessed by serum creatinine, urinary excretion of albumin in a random urine sample corrected by creatinine, creatinine clearance calculated based on the Cockroft and Gault formula[18] and glomerular filtrate estimated by means of the simplified *Modification of Diet in Renal Disease* formula.[19] All data should have been no older than 6 months.

Statistical analysis

Data are expressed by means (standard deviation [SD]) for normally distributed continuous variables, by median (interquartile range) for continuous variables with non-Gaussian distribution, or by frequencies and percentages for categorical variables.

Differences among controlled or non-controlled patients were analysed by means of bilateral hypothesis tests with the *t*-Student test, the Mann–Whitney non-parametric test, or chi-square test, as appropriate. The analysis of 3 groups used the Cochran–Armitage statistic (tendency test). A logistic regression analysis (stepwise forward method) was conducted with the variables that showed a significant or nearly significant difference ($p < 0.1$) in the simple analysis.

Results

Degree of blood pressure control

The study involved a total of 1,337 patients, 785 male patients and 552 female patients (41.3%), with a mean age of 63 (12) years. Clinical characteristics are shown in Table 1.

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