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Primary Care Diabetes

journal homepage: <http://www.elsevier.com/locate/pcd>PCDE  
primary care diabetes europe

## Original research

# Pharmacological control of diabetes and hypertension comorbidity in the elderly: A study of “real world” data

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## ARTICLE INFO

## Article history:

Received 21 September 2016

Received in revised form

23 January 2017

Accepted 20 March 2017

Available online xxx

## Keywords:

Comorbidity

Diabetes mellitus

Hypertension

Drugs

Control

Medication adherence

Primary health care

## ABSTRACT

**Aims:** The study aimed to determine which drug combinations achieve better control in comorbid diabetes and hypertension in a pragmatic sample of primary health care patients. **Methods:** Cross-sectional study. Setting: 251 primary health care centres in Catalonia, Spain. **Participants:** individuals  $\geq 65$  years old with a dual diagnosis of hypertension and diabetes. **Main outcome measures:** good control criteria were established as glycated haemoglobin  $\leq 7\%$  and blood pressure  $< 140/90$  mm Hg. Antihypertensive and hypoglycaemic drugs and treatment adherence were analysed in relation to their association with good control.

**Results:** 27,637 patients (58.0% women) had hypertension and diabetes and met selection criteria. Mean age was 75.9 years (standard deviation [SD]: 6.7). Both diseases were well controlled simultaneously in 34.2% of patients. The combination of biguanides and diuretics achieved the highest association with good control. Adherence to pharmacological treatment was more difficult in diabetes than in hypertension.

Lack of control was associated significantly with non-adherence to treatment, 0–12 PHC visits, obesity and increasing number of diabetes prescriptions.

**Abbreviations:** PHC, primary health care; CPG, Clinical Practice Guidelines; RCTs, randomized clinical trials; EHR, electronic health records; SIDIAP-Q, Information System for the Development of Research in Primary Care- Quality; BP, blood pressure; HbA1c, glycated haemoglobin; ICD-10, International Classification of Diseases version 10; BMI, body mass index; CVR, cardiovascular risk; ATC, Anatomical Therapeutic Chemical; DDD, defined daily doses; MPR, Medication Possession Ratio; SD, standard deviation; IQR, interquartile range; GCG, group with good control; PCG, group with poor control; ACEi, angiotensin-converting-enzyme inhibitor; OR, odds ratio; ARBs, Angiotensin II Receptor Blockers; CCBs, calcium-channel blockers.

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<http://dx.doi.org/10.1016/j.pcd.2017.03.007>

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**Conclusions:** Good control of diabetes and hypertension comorbidity with pharmacological treatment in elderly patients is challenging. Some drug combinations achieved better control than others. The greatest effort should focus on improving the low adherence to diabetes treatment.

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## 1. Introduction

In primary health care (PHC) records in European countries, there is an increasing trend of patients being diagnosed with diabetes mellitus and hypertension as comorbidities [1,2]. More than 50% of diabetes patients have concomitant hypertension, which contributes significantly to micro- and macrovascular complications in these patients [3]. These two diseases constitute the circulatory-endocrine-metabolic pattern, the leading pattern in older adults in the majority of multimorbidity studies in this population [4,5]. Furthermore, the coexistence of hypertension and diabetes is associated with increased costs and resource utilization [6–8].

Optimal control of diabetes and hypertension in the elderly is a challenge in PHC because these patients frequently have functional disabilities, cognitive decline, multimorbidity and polypharmacy, and are also more likely to have hypoglycaemic events. Adherence to healthy behaviours and prescribed medications is the cornerstone of control to avoid cardiovascular complications of this comorbidity pattern [9,10]. Until now, however, prescription of drug combinations has followed Clinical Practice Guidelines (CPG) or Randomized Clinical Trials (RCTs) recommendations. The CPG recommendations have been criticized for relying on expert opinions and RCTs frequently include a non-representative sample of patients, which may limit their external validity [11]. Consequently, there is a growing interest in access to real-world data to evaluate the effects of drug combinations. Electronic health records (EHR) databases allow health professionals to track information on their patients over time and also have some advantages over prospective data collection (used in RCT or observational studies), such as heterogeneity and better representation of the patient population in actual clinical practice [12,13]. This data source has been perceived as a powerful research tool in profiling drug use and adherence [14,15].

Knowledge of the most effective drug combination to control this prevalent comorbidity pattern may contribute to improving prescription protocols. The purpose of this study was to determine which drug combinations achieved good control in a higher percentage of patients with diabetes and hypertension in a pragmatic sample of primary health care records.

## 2. Methods

### 2.1. Design, setting and study population

A cross-sectional epidemiological study was designed. Methodological aspects of data source and study population have been published in detail elsewhere [16]. Briefly, a sam-

ple of 343,352 patients aged 65 years or older who visited one of 251 PHC centres in Catalonia during the study period, January 1, 2009 through December 31, 2010, was selected from a high-quality EHR database (SIDIAQ-Q, the Catalan acronym for “Information System for the Development of Research in Primary Care- Quality”). The flow chart of the study is shown in Fig. 1.

### 2.2. Eligibility criteria

The study sample was limited to patients with a diagnosis of diabetes and hypertension in the EHR before January 1, 2008 and values of blood pressure (BP) and glycated haemoglobin (HbA1c) measures registered in the EHR during the study period. All International Classification of Diseases version 10 [ICD-10] codes were included for diabetes mellitus (E10-E14) and hypertensive diseases (I10-I15).

Included patients met the following criteria: i) aged 65 years or older on 31 December 2010; ii) filled at least one prescription for diabetes and for hypertension medication during the study period; and iii) had at least one BP and one HbA1c measurement within 3 months during the study period (if multiple measurements were available, the pair taken within the narrowest timeframe was selected).

### 2.3. Variables definition

Criteria for good control were established according to local, European and international guidelines in force during the study period [17–19]. Good blood pressure (BP) control was defined as <140/90 mmHg and diabetes control as HbA1c  $\leq$  7%. Patients were considered to be well controlled when both criteria were met.

Demographic variables (age and sex), body mass index (BMI) (weight in kilograms divided by the square of height in meters [ $\text{kg}/\text{m}^2$ ]), obesity (BMI  $\geq$  30  $\text{kg}/\text{m}^2$ ), smoking status (never smoked, ex-smoker, current smoker), type of diabetes mellitus (1 vs 2), and systolic BP and diastolic BP measurements (mmHg) were recorded. Laboratory test parameters included HbA1 (%) ; glomerular filtration rate ( $\text{ml}/\text{min}/1.73 \text{ m}^2$ ), characterized as normal [20] or abnormal; triglycerides (mg/dl) and total cholesterol (mg/dl). The highest number of PHC visits (doctor, nurse and social worker) in any 6-month period:  $\geq$  12 versus 0–11 visits and Charlson comorbidity index ( $\leq$  3 vs  $>$  3) [21]. In patients aged 65–74 years, cardiovascular risk (CVR) score was calculated (Registre Gironí del Cor, REGICOR) and categorized as low (<5%), mild (5%–9.9%) or high ( $\geq$  10%) [22].

Antihypertensive and hypoglycaemic drugs were selected according to the WHO’s Anatomical Therapeutic Chemical (ATC) classification system (Annex 1 in Supplementary data).

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