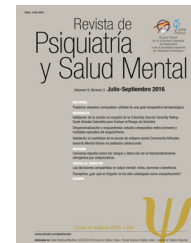




Revista de Psiquiatría y Salud Mental

www.elsevier.es/saludmental



ORIGINAL ARTICLE

Trazodone utilization among the elderly in Spain. A population based study

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Received 14 June 2016; accepted 10 November 2016

KEYWORDS

Trazodone;
Drug utilisation
study;
BIFAP

Abstract

Introduction: Trazodone was authorized for the treatment of depression in the 1970s. Several additional therapeutic uses have been proposed due to its heterogeneous mechanism. This study aims to determine the use of trazodone in the elderly in Spain.

Methods: A nationwide, longitudinal and descriptive analysis was conducted using data from patients aged >65 years with a first prescription of trazodone during the period 2002–2011. Information on dose, comorbidities and relevant co-medication was gathered from the Spanish Primary Care database BIFAP. Incidence rates of trazodone use per 10,000 person-years were calculated by sex and age.

Results: A total of 11,766 patients receiving a first prescription of trazodone were included. The incidence rate of trazodone use was 47.2 (95% CI: 46.33–48.04) per 10,000 person-years. An increasing trend in the use of trazodone was observed (5-fold increase in 2011 as compared to 2002). The most common therapeutic indications were: depression (21.41%), Alzheimer/dementia (20.36%), sleep disorders (16.22%), and anxiety disorder (8.91%). The median dose was 100 mg/day. The use of trazodone concomitantly with interacting medicines was frequent: anti-hypertensives (53.60%), and CNS depressors (59.32%).

Conclusions: Trazodone use is increasing in elderly patients, and a high proportion of use in non-approved indications was observed. Trazodone is not being used at high doses, but interacting medicines were frequent, and it may pose additional risks for elderly patients.

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PALABRAS CLAVE

Trazodona;
Estudio de
utilización;
BIFAP

Utilización de trazodona en ancianos. Un estudio de base poblacional

Resumen

Introducción: La trazodona se autorizó para el tratamiento de la depresión en los años 70, y se han propuesto otros usos por su mecanismo de acción heterogéneo. Este estudio tiene como objetivo caracterizar la utilización de trazodona en ancianos en España.

Métodos: Se llevó a cabo un análisis longitudinal en pacientes > 65 años con una primera prescripción de trazodona durante el periodo 2002-2011. Se obtuvo información a partir de datos de BIFAP sobre la dosis, indicaciones, comorbilidades y medicación concomitante. Se calcularon las tasas de uso por 10.000 personas-año por grupos de edad (66-75; >75) y sexo. Se llevó a cabo un análisis descriptivo de las principales indicaciones y la medicación.

Resultados: Se identificaron 11.766 pacientes con una primera prescripción de trazodona en el periodo de estudio. La tasa de incidencia de utilización fue de 47,2 (IC95%: 46,33-48,04) por 10.000 personas-año. El uso se quintuplicó en 2011 respecto a 2002. Las indicaciones terapéuticas más frecuentes fueron: depresión (21,41%), enfermedad de Alzheimer/demencia (20,36%), trastornos del sueño (16,22%), trastorno de ansiedad (8,91%). La mediana de la dosis fue 100 mg/día. El uso de medicación concomitante que podría interaccionar fue frecuente: antihipertensivos (53,60%) y depresores del sistema nervioso central (59,32%).

Conclusiones: La utilización de trazodona ha aumentado en pacientes ancianos y se ha registrado una gran proporción de uso en indicaciones no autorizadas. El empleo de trazodona a dosis altas es infrecuente, sin embargo una gran proporción de pacientes estaban siendo tratados con medicamentos que interaccionan con trazodona y que podrían aumentar el riesgo en ancianos.

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Introduction

Trazodone was originally licensed in Europe and U.S. for the treatment of depression¹ and is available since the 70s. Whereas its neuropharmacology is not fully understood, trazodone has been defined as a multifunctional drug. Its activity inhibiting the serotonin reuptake and antagonism on the 5HT₂ receptors and alpha-1 adrenergic receptors is well recognized. In addition, a moderate antihistaminic activity and a low anticholinergic and dopamine activity have been described.² Rare adverse reactions like hepatotoxicity or arrhythmia have been reported.³ However some of the most common adverse reactions of trazodone seem to be dose-dependent and include orthostatic hypotension, dizziness, somnolence and syncope.^{4,5} Furthermore, trazodone adverse effects can be more common in the elderly compared with younger groups due to its higher distribution volume, higher levels of comorbidity, age related physiological changes, and polypharmacy.^{4,6,7}

The trends of trazodone utilization in current clinical practice in Spain have not been studied. Information about the clinical profile of the treated elderly patients is scarce. In this context, this study examines the trends of utilization of trazodone and analyzes the pharmacological pattern of trazodone utilization, including the study of relevant co-medication which may increase the risk for adverse reactions in the elderly.

Methods

Setting

A descriptive study was conducted in BIFAP (*Base de Datos para la Investigación Farmacoepidemiológica en Atención Primaria*), an electronic health care database from Spain. BIFAP is a longitudinal population-based database managed by the Spanish Agency for Medicines and Medical Devices collecting computerized medical records from 4871 general practitioners (GPs) throughout Spain from 2001 onwards. This database includes anonymized information on 7,603,394 patients, accounting for 38,649,688 person-years of follow up.⁸

The dataset is comparable to the Spanish population with respect to its age and sex distribution. Data recorded in BIFAP include demographic information, prescription details, clinical events, specialist referrals and laboratory test data.⁹

Study population

From the BIFAP database, we included patients aged >65 years old with at least one year of registration with a GP, and who received at least one trazodone prescription, between

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