



NEUROLOGÍA

www.elsevier.es/neurologia



ORIGINAL ARTICLE

Descriptive analysis of the use of atypical antipsychotics under compassionate-use in a health area in Ferrol (La Coruña, Spain)

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Received on 17th June 2009; accepted on 11th January 2010

KEYWORDS

Agitation;
Anti-psychotic;
Behaviour;
Dementia;
Neuroleptic drugs;
Quetiapine

Abstract

Background and objective: Although atypical antipsychotics (AA) provoke fewer extra-pyramidal symptoms (ES) than classic antipsychotics, their use in patients greater than or equal to 75 years old with dementia must be under compassionate-use. This is an important limitation. We performed a descriptive analysis of the use of atypical antipsychotics under compassionate-use (AACU) in the Ferrol health area.

Patients and methods: We retrospectively assessed all the patients who were receiving an AACU from March, 2004 (that is the date when prescription under compassionate-use of AA came into force in Spain) to 30 November, 2008.

Results: One hundred and thirty-three of 164 patients (63.6% women; median ages, 81.9±4.95 years) were included. Diagnostic aetiologies were: 42.9% Alzheimer disease, 30.8% Parkinson-dementia/Lewy body disease, and 15.8% vascular/mixed dementia. A total of 68.4% of patients had received other anti-psychotic drugs previously and 32.3% had ES due to antipsychotics. The AACU received were: quetiapine (76.7%), ziprasidone (18.8%), and olanzapine (4.5%). Median follow-up time was 20.25±20.38 months. Side effects were observed in 19.7% of patients. Improvement of NPI (Neuropsychiatric Inventory) was 33.3±24.75 points. Agitation/aggressiveness (5.6±4.55), delirious ideas (4.94±5.07), irritability (4.38±4.94), and anxiety (4.32±4.83) were the symptoms that most improved. Although there were no differences between AACU, quetiapine was associated with significant maintenance in monotherapy (94.1% vs 72% for ziprasidone and 83.3% for olanzapine; $p<0.0001$).

Conclusions: AACU are effective and well tolerated drugs. Quetiapine was the most frequently used AACU. An excessive percentage of patients previously received other antipsychotics and present with ES.

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PALABRAS CLAVE

Agitación;
Antipsicótico;
Demencia;
Neuroléptico;
Quetiapina;
Trastorno conductual

Análisis descriptivo de la prescripción de antipsicóticos atípicos de uso compasivo en el área sanitaria de Ferrol

Resumen

Objetivos: Aunque quetiapina y ziprasidona producen menos síntomas extrapiramidales (SEP) que otros antipsicóticos, su uso en pacientes mayores de 75 años con demencia se ve condicionado por la obligatoriedad de prescribirlos "por uso compasivo". Realizamos un análisis descriptivo del uso de antipsicóticos atípicos de uso compasivo (AAUC) en el área sanitaria de Ferrol.

Pacientes y métodos: Incluimos a todos los pacientes que recibieran un AAUC desde marzo de 2004 (fecha en que entró en vigor la dispensación de AAUC) hasta el 30-11-2008.

Resultados: Se incluyó a 133 de un total de 164 pacientes (el 63,6%, mujeres; media±desviación estándar de edad, 81,9 ± 4,95 años). El 94,1% presentaba demencia (el 42,9%, enfermedad de Alzheimer; el 30,8%, demencia-enfermedad de Parkinson, y el 15,8%, demencia vascular/mixta). El 68,4% había recibido algún otro antipsicótico previo y el 32,3% presentaba SEP secundarios. Los AAUC prescritos fueron: quetiapina (76,7%), ziprasidona (18,8%) y olanzapina (4,5%). La media de tiempo de seguimiento fue 20,25 ± 20,38 meses. El cumplimiento terapéutico fue del 95,5%. El 19,7% presentó efectos secundarios. La media de mejora en la escala NPI (Neuropsychiatric Inventory) fue 33,3 ± 24,75 puntos. La agitación/agresividad (5,6 ± 4,55), las ideas delirantes (4,94 ± 5,07), la irritabilidad (4,38 ± 4,94) y la ansiedad (4,32 ± 4,83) fueron los síntomas que más mejoraron. Aunque no hubo diferencias entre los 3 AAUC, quetiapina conllevó un mayor mantenimiento en monoterapia (el 94,1 frente al 72% de ziprasidona y el 83,3% de olanzapina; $p < 0,0001$).

Conclusiones: Los AAUC son fármacos efectivos y bien tolerados. Quetiapina es el AAUC más utilizado. Un porcentaje excesivo de pacientes reciben antes otros antipsicóticos y presentan SEP.

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Introduction

Neuroleptics are drugs commonly used in neurology for the control of behavioural symptoms in patients with dementia; in particular, atypical antipsychotics (AA) stand out due to their reduced ability to induce or exacerbate extrapyramidal symptoms (EPS). Risperidone presents a pharmacological profile that is more similar to classical neuroleptics,¹ and finding cases of Parkinsonism secondary to it in consultation is commonplace. Ziprasidone, olanzapine, and, especially, quetiapine and clozapine are AA that cause less EPS.² In contrast, their prescription in all patients without a diagnosis of schizophrenia / manic episodes (in practice, in patients who are 75 or older) is conditioned by the requirement of processing its use as compassionate (currently classified as drugs in conditions other than those authorised within the regulations on the availability of drugs in special situations, RD 1015/2009 from 19th June, Chapter III). This is an obvious drawback, when we consider that many of the patients who require it are of advanced age, especially those with dementia and behavioural disorders. In this sense, clinical experience accumulated during the treatment of patients with cognitive impairment and behavioural disorders probably points towards a predominant initial use of classical neuroleptics or risperidone among AA.

This article presents a detailed descriptive analysis of the use of AA prescribed by experts and administered to

patients in the Ferrol health district by the Pharmacy Service of Hospital A. Marcide through compassionate use.

Patients and methods

We conducted an epidemiological, observational, non-interventionist, population, descriptive, retrospective study that included all patients who were receiving or had received one or more AA for compassionate use (AACU), administered by the Pharmacy Service of Hospital A. Marcide in Ferrol, from March 2004 (the date on which the dispensing of AACU was enforced) to 30 November 2008. The following exclusion criteria were considered: patients younger than 75 years, patients with unavailable information (in their history and/or registry of pharmacy data) required in the study for further analysis, and patients who refused (or their relatives did) to give informed consent to participate in the study.

As a hypothesis, we considered, according to our experience, that AACU were probably prescribed in a higher percentage of cases as a second option after others that had already caused EPS or other side effects or that had not been effective.

The main objective of the study was to carry out a descriptive analysis of the use of AACU prescribed in the health area of Ferrol and to learn the following data, among others: the most commonly prescribed drug, prescribing service, most frequent symptoms, most frequent diagnosis,

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