

Use of dopamine agonist drugs in clinical practice: a population-based study in the years 2004-2010

G. Starvaggi¹, R. Ferrara¹, D. Italiano¹, G. Trifirò¹, A. Cannata¹, C. Pagliaro², I. Lombardi², D.U. Tari², M. Tari², C. Ferrajolo³, A. Capuano³, E. Spina¹, V. Arcoraci¹

¹Dept of Clinical and Experimental Medicine, University of Messina, Italy; ²Caserta Local Health Unit, ³Dept. of Experimental Medicine, Pharmacology Section, Second University of Napoli, Italy.

Background

The use of Dopamine agonists (DA) has been progressively increasing in the last years, for both the treatment of Parkinson disease (PD) and hyperprolactinemia (HP). Starting from 2002, an increased risk of valvular heart disease associated with the use of Ergot-derived pergolide and cabergoline in patients with PD was shown. As a consequence, in March 2007, pergolide was withdrawn from the market in USA. Starting from July 2008, according to European Medicines Agency, the Italian National Agency (AIFA) introduced a risk minimization measure, by modifying the summary of product characteristics and decreased the maximum dispensable dose of cabergoline and pergolide to 3 mg/day. Moreover echocardiographic monitoring is required both in PD or HP affected patients.

Aim

To evaluate the prescription pattern of DA in general practice during the years 2004-2010; to characterize the DA users; to assess the trend of use of ergot- and non-ergot-derived in the treatment of PD or HP.

Methods

Data were extracted from the General Practitioners Caserta Local Unit Arianna database. Patients over 14 who received at least one DA drug prescription during the follow up period, were identified. The DA use was calculated as one-year prevalence and incidence. Sub-analyses by gender, age and indication of use have been performed.

Results

Prevalence of DA use slightly increased (from 4.5/1000 inh. in 2004 to 6.5/1000 inh. in 2008), remaining stable during the last years. A similar trend was observed in new users. A stable trend of DA use was observed in patients affected by prolactin disorders treated with ergot-derived drugs (2.9/1000 inh. in 2004 to 2.5/1000 inh. in 2010). No use was reported for non-ergot-derived DA. By contrast, in PD, non-ergot-derived DA use increased during the follow-up period (0.8/1000 inh. in 2004 to 2.9/1000 inh. in 2010) while ergot-derived use fell starting from 2007 (0.5/1000 inh. in 2004 to 0.1/1000 inh. in 2010). Cabergoline use increased from 4.3/1000 inh. in 2004 to 8.2/1000 inh. in 2nd quarter of 2006, followed by a straight decrease (0.4/1000 inh. in 2010). Starting from 2006 a decreasing mean dose of cabergoline was observed and starting from July 2008 no patients treated with more than 3 mg/day were found. A trifling and decreasing use of pergolide for PD was observed. Conversely a stable use of cabergoline was observed in HP affected patients (1.2/1000 inh. in 2004 to 1.2/1000 inh. in 2010)

Discussion

An increased use of DA, was mainly observed in PD affected patients. However, while a progressive rise of non-ergot-derived DA was observed, ergot-derived DA strongly decreased. Particularly the results of our study indicate a decrease in both prevalence and incidence of cabergoline use starting from 2006 only for the treatment of PD and a marginal pergolide use for the same indication. This evidence might be a consequence of international and national regulatory restrictions due to the increased risk of cardiac valve regurgitation associated to pergolide and cabergoline. Conversely no changes in cabergoline use have been observed for the treatment of HP. Our findings underline how health regulatory measures represent a more efficient tool in influencing the prescribing behavior, rather than drug use knowledge.