Safety of Antipsychotic Drugs in Paediatric patients

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Background: The drug safety in pediatric patients is a crucial issue of pharmacovigilance. Safety and efficacy data related to drugs use in children are very few. Moreover, the shift of data from adult patients to paediatric patients may be incorrect and may give rise to errors in dosing. Approximately the 60% of children prescriptions is *off-label*. For these reasons, the detection of suspected adverse drugs reactions (ADR) during the *post-marketing* represents the most important source of information to define the drug safety profile in children [1, 2].
Objective: The primary objective is to assess the safety of antipsychotics in children and compare the safety profile of risperidone with other drugs included in the study (aripiprazole, olanzapine and quetiapine).
Methods: The study predicted the involvement of children and adolescents aged ≤ 18 years, naive or in treatment with Second generation of Antipsychotic (SGA) (aripiprazole, olanzapine, quetiapine and risperidone). for the study was provided a 12 months period, during which patients were subjected to a periodic clinical evaluation (every 4 weeks). The prescriber and monitor have collected data through an ad hoc process. The collected data are blood and cardiology routine parameters, and clinical pharmacological aspects directly related to treatment with atypical antipsychotics.
Results: The study is still ongoing. The preliminary data show that 161 patients were enrolled; the 64% of patients enrolled presented a comorbidity, while 36% more than one comorbidity. The 24.2% of patients enrolled was naive to treatment with antipsychotic medications. The results also showed that the switch was practiced in 19.9% of patients; in particular, the 11.2% of patients (N = 8) in treatment with risperidone shift to aripiprazole, while 4.3% of patients (N = 7) treated with aripiprazole shift to risperidone. Safety analyses showed that 25.5% of patients treated with SGA presents an ADR while the 28.2% of patients presented more of an ADR. Altogether, it was verified the onset of 166 ADR. In the 28% of patients has been found the adverse reaction *"therapeutic failure"*. The ADRs onset more frequently were gastrointestinal disorders (20 %), central nervous system disease (20 %), metabolic disorders (21 %), hormonal disorders (20%) and cardiovascular disease (10 %).
Conclusions: The study will evaluate the safety profile of SGA in the paediatric patients and the effectiveness by the estimation of the therapeutic failures.

Bibliography

[1]. European Agency of Medicine (EMA) 'Guideline on conduct of pharmacovigilance for medicines used by the pediatric population'. http://www.ema.europa.eu/pdfs/human/phvwp/23591005enfinal.pdf.
[2]. Napoleone E. Children and ADRs (Adverse Drug Reactions). Ital J Pediatr. 2010;36:4.
[3]. Ben Amor L. Antipsychotics in pediatric and adolescent patients: a review of comparative safety data. J Affect Disord. 2012;138:S22-30.