TOLERABILITY OF ANTIPSYCHOTICS IN CHILDREN AND ADOLESCENTS: A PROSPECTIVE STUDY

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Background: In the last decade, an increased use of antipsychotics in children and adolescents has been reported in Western Countries. However, there is growing concern about actual safety of these agents in paediatric setting since psychotropic medications are commonly prescribed off-label to children. Moreover, the assessment of benefit/risk ratio of antipsychotic use in children and adolescents is mainly based on data derived from case reports and small open-label trials, while few observational investigations have been conducted so far. **Objective**: A prospective, longitudinal study was performed in a pediatric setting to assess incidence rate of adverse drug reactions (ADRs) with antipsychotics during the years 2003-2006. **Methods**: All patients 18 years old or younger, who started a treatment with antipsychotics during the study years in two Child Neurology and Psychiatry Units of Southern Italy, were followed up during the first three months of therapy, irrespectively of diagnosis. All clinical information and adverse drug reactions eventually occurred, were regularly collected by physicians during their daily clinical practice in a form ad hoc created. Parents were informed about off-label use of medications and potential adverse reactions, in order to receive informed consent before starting any antipsychotic treatment. Patients received at least one follow-up visit every month for three months consecutively after the beginning of therapy. **Results**: Overall, 156 patients younger than 18 years, who started a therapy with antipsychotics were recruited. Of these,106 (68%) were males and 50 (32%) were females. The mean age was 11.4±4.2. Within the study sample, 31 (20%) received a typical antipsychotic, 100 (64%) an atypical antipsychotic, 25 (16%) patients took both medications . Concerning ADRs, 80 patients (51%) reported a total of 150 ADRs during the first three months of therapy, leading to drug discontinuation in 29 patients (18%). ADRs that more frequently occurred during therapy with typical antipsychotics were weight gain (N= 7, 23%) and sleepiness (5, 17%). Similarly, the most reported ADRs due to atypical antipsychotics were weight gain (21, 17%), sleepiness (16, 13%) and hyperfagia (12, 10%). **Conclusion**: Adverse drug reactions frequently occurred with antipsychotics during the first 3 months of therapy in children and adolescents. This prospective study might provide new insights about tolerability and ADR occurrence in children and adolescents treated with antipsychotic medications.