PHARMACOVIGILANCE IN CHILD NEUROPSYCHIATRY: MULTIDISCIPLINARY PROJECT AT THE IRCCS BURLO GAROFALO

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Introduction: In the treatment of psychiatric pathology, particularly in the developmental age, the choice of the appropriate drug requires a careful assessment of the risk/benefit profile, to avoid or minimize the occurrence of adverse drug reactions (ADR). In order to improve the appropriateness and safety of care, a structured multidisciplinary monitoring was launched.

Materials and methods: Prospective study of the impact assessment of active pharmacovigilance comparing historical cohort 2016-2018 (without active surveillance) and active cohort 2019-2020; patients aged 0-18 years, with admission or access to Day Hospital/ambulatory in Child Neuropsychiatry of the IRCCS Burlo Garofolo. The project involves a multidisciplinary pharmacovigilance activity (physician-pharmacist) through the detection of ADRs, drug interactions and the safety comparison between off-label and on-label drugs.

Results: From the retrospective analysis of patients admitted to the NPI between 2016 and 2017, it was found that out of the total 338 patients, those with psychiatric diagnosis were 112 (33%); Males n = 53, Females n = 59, average age 14 years). Out of 269 prescriptions of drugs found, the top ten drugs were: promazine 13%, delorazepam 12%, clotiapine 8%, risperidone 8%, quetiapine 6%, carbolithium 4%, fluoxetine 4%, aripiprazole 3%, trihexyphenidyl 3%, olanzapine 3%. The average number of drugs taken per patient was 3. 34% of the prescriptions were found to be off-label. The drugs most commonly prescribed outside the authorized indications were: delorazepam (27%) off-label by age, quetiapine (17%) off-label by age and indication (mood disorder and of impulses), trihexyphenidyl (9%) off-label for age and indication (used to counteract the side effects of antipsychotics, prescription cascade) and olanzapine (7%) off-label for age and indication (anorexia). 26 total ADRs were detected: according to the Naranjo algorithm 58% were probable, 35% possible and 7% doubtful; 12 ADRs was associated with on-label drugs use and 14 with off-labels, of which 4 ADRs were classified as serious (2 from on-label drugs and 2 from off-labels). On average patients who experienced ADR were taking more drugs than patients without any ADR (5 vs 3). According to the Drug Interaction Probability Scale (DIPS) algorithm, 46% of ADRs were due to possible drug interactions.

Discussion and conclusions: The preliminary outcomes of the study show slightly higher frequency of ADRs in patients treated with off-label drugs, an increased risk of developing ADRs associated with polypharmacy and greater appropriateness in prescription with medical-pharmacist intervention. The study aims to collect clinical evidences on the safety of off-label pharmacological therapies by using multidisciplinary pharmacovigilance monitoring and to optimize the prescription pathway based on the best evidence level.