



Το Αλλεργικό Παιδί και οι Εξελιξείς

ROYAL OLYMPIC HOTEL | ΑΘΗΝΑ

02-05 ΦΕΒΡΟΥΑΡΙΟΥ 2023

www.allergycongress.gr

Severity and Risk Factors of Allergen Immunotherapy Adverse Events in Children and Adolescents with Respiratory Allergies – Data from ADverse Events Registry (ADER).

Dimitrios I Mitsias 1, Julijana Asllani 2-3, Maria Alefantou 1, Nikolaos G Papadopoulos 1, ADER Study group

1. Allergy Unit, 2nd Pediatric Clinic, University of Athens, Athens, Greece
2. University of Medicine Tirana, Tirana, Albania.
3. Allergy and Asthma Medical Clinic, Tirana, Albania

BACKGROUND: Real life data on allergen Immunotherapy (AIT) safety in children are scarce though it is demonstrated that both subcutaneous (SCIT) and sublingual (SLIT) immunotherapy are generally well tolerated. We aim to evaluate the severity of adverse events (AE) and risk factors in children and adolescents.

METHODS: Adverse Events Registry (ADER) is the first multinational registry assessing AIT safety in real life. Centers from eight countries (Albania, Bulgaria, Croatia, Greece, Romania, Serbia, Slovenia and Turkey) contributed to the registry. Patients under 18 years old with allergic rhinitis and/or asthma undergoing SCIT and/or SLIT with pollen, mites, epithelia and/or molds were retrieved. Severity of systemic and local AE, symptoms according Medical Dictionary for Regulatory Activities (MedDRA) terminology, timing and treatment were recorded and analyzed. Risk factors associated with adverse reactions were investigated as well.

RESULTS: Data on 851 patients, 480 (56.4%) children and 371 (43.6 %) adolescents, undergoing 998 AIT courses (51% SCIT, 49% SLIT) were analyzed. Patients had allergic rhinitis in 47.6% of cases, rhinitis and asthma in 44.5% and asthma in 7.9%. Most common sensitization was to pollen (57.1%), followed by mites (53.4%), alternaria (18.2%) and epithelia (16.7%); 53% of the patients had multiple sensitizations. However, 84.5% were single allergen AIT. Out of 250 AE the majority (83.1%) was mild and only 6 severe reactions occurred in 4 patients (0.4%). The majority (87%) had an early onset (<30 minutes) and, among severe AE, none was observed after 6 weeks of maintenance. The most common symptoms according to MedDRA terminology were cough (48%), rhinitis (43%), dyspnoea (11%) and chest tightness (9%). Epinephrine was used in only 6 occasions (4/6 were severe). Several potential risk factors were evaluated yet only SCIT was found to be associated with a higher risk for AE (15.5% vs. 4.9% for SLIT). Only one severe reaction occurred with SLIT for an adolescent with active gastric ulcer.

CONCLUSION: Our data are reassuring that SCIT and SLIT are well tolerated in children though SCIT was associated with a higher risk for AE. Severe reactions (0.4% of cases) and discontinuation of AIT (0.4% of cases) were very rare