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Efficacy And Safety of Allergen-Specific Immunotherapy in Children with Asthma

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Abstract: Pediatric asthma is a common chronic respiratory disease that severely affects the quality of life and daily functioning of children affected by the disease. Allergen-specific immunotherapy (AIT) has developed as a possible disease-modifying intervention as its objective is to correct the underlying immune dysregulation, beyond just providing symptomatic relief. The present investigation aimed to evaluate the efficacy and safety profile of AIT in a paediatric group of asthmatic patients. A total of 120 children, 6-14 years old, were recruited, of which 80 children received AIT in combination with standard therapy, while 40 children were treated with conventional therapy only. Clinical outcomes, pulmonary function, immunologic parameters, and adverse events were systematically assessed for a 12 to 36-month follow-up period. The results showed significant reductions in symptom frequency, the need for rescue medications, and improvements in pulmonary function in the AIT cohort. Immunologic analyses showed decreases in serum IgE and eosinophil count and alterations in the cytokine profiles, indicating increased immune tolerance. Adverse events were mostly mild and transient in nature and support the idea of a favourable safety profile. Overall, AIT improved clinical, physiological and psychosocial outcomes and hence provided support for its inclusion in the management of paediatric asthma.

Keywords: Allergen-specific immunotherapy, Pediatric asthma, Clinical outcomes, Immunological markers, Safety, Quality of life

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1. Introduction

Perovskite Pediatric asthma is among the most common types of chronic respiratory diseases in children worldwide and has a major impact on quality of life, school attendance and healthcare utilisation. Its multifactorial aetiology of genetic susceptibility, environmental exposures and immune dysregulation makes early diagnosis and effective management particularly complex. Recent epidemiological investigations suggest a sustained rise in the prevalence of paediatric asthma, especially in the urbanised areas with a greater burden of allergens, pollutants and respiratory infections. The burden of the disease, however, is increasing further, and thus underlines the need for innovative therapeutic strategies to move beyond conventional pharmacotherapy [1].

Allergen-specific immunotherapy (AIT), and in particular under its two main forms, subcutaneous (SCIT) and sublingual (SLIT), has become a promising intervention that attempts to modulate the underlying immune response, rather than treating the symptoms. AIT aims to induce long-term tolerance against discrete allergens by modulating T cell activity, enhancing regulatory processes and diminution of IgE

mediated hypersensitivity. In paediatric cohorts, immunotherapy provides the possibility not only of improving symptom control but also of preventing disease progression and of reducing the risk of the subsequent development of atopic manifestations, such as allergic rhinitis or atopic dermatitis. Nevertheless, its implementation is still limited by the apprehensions about safety, adherence and optimal dosing regimens [2].

Variability in the therapeutic response has been noted in several studies, corresponding to heterogeneity of the patients (age, severity of the disease, profile of allergens, individual immunological setting). While some of the children show substantial clinical improvement and a decrease in medication dependency, others show adverse reactions ranging from mild local manifestations to the rare incidence of systemic reactions. This variability highlights the need for detailed evaluation of both efficacy and safety parameters when considering AIT for children with asthma [3].

Emerging evidence also appears to tilt in favour of combining immunotherapy with traditional treatment regimens to optimise clinical outcomes. For example, the use of AIT in conjunction with inhaled corticosteroids or leukotriene receptor antagonists has been found to improve symptom control with the possible reduction of exposure to the drug. This integrated approach is in line with the current move towards personalised medicine with a focus on therapeutic plans based on individual patient characteristics, allergen sensitivities and risk profiles [4].

Given the rising prevalence of paediatric asthma, as well as the prospective benefits of immunotherapy, there is clearly a need for systematic assessment of the safety and efficacy of immunotherapy in real-world paediatric populations. The current study, therefore, aims to assess clinical outcomes, immunological responses and adverse event profiles linked to AIT in children with asthma, in order to provide evidence that can be used for clinical decision-making and optimisation of clinical management approaches [5].

2. Methodology

This was a prospective observational study of the effectiveness and safety of allergen-specific immunotherapy (AIT) in children with asthma. The cohort consisted of 120 participants aged between 6 and 14 years referred to the Pediatric Allergy and Immunology Clinic of the Tashkent State Medical University between January 2023 and December 2024. All subjects had a confirmed diagnosis of asthma, based on clinical evaluation, spirometric measure and allergy tests, under Global Initiative for Asthma (GINA) guidelines. Exclusion criteria were severe uncontrolled asthma, chronic pulmonary diseases or other immunodeficiencies, as a way to minimise confounding variables and ensure participant wellbeing [6].

Participants were divided into two groups: those receiving AIT by subcutaneous or sublingual injection were divided into 80 children, who were given AIT in addition to the standard pharmacological regimen, consisting of ICS and LTA together; while 40 children continued in the conventional therapy alone, which was the control group. Selection of the type of immunotherapy (SCIT vs SLIT) was based on allergen sensitivity, patient preference and clinical suitability. Treatment duration lasted from 12 to 36 months with prearranged follow-up visits every 3 months for clinical assessment and monitoring of possible adverse reactions [7].

Allergen selection was based on skin prick testing and serum-specific IgE testing for common aeroallergens (house dust mites, pollens, pet dander and moulds). At each visit, clinical outcome was measured in terms of symptom scores, asthma control questionnaires and pulmonary function indices such as forced expiratory volume in one second (FEV1) and peak expiratory flow rate (PEFR). Safety evaluation was done in terms of local and systemic adverse events, which were categorised based on World Allergy Organisation (WAO) guidelines. Nocturnal symptoms, rescue medication use, and exercise-induced events were recorded daily on symptom diaries by the parents [8].

Laboratory analyses were conducted at baseline, 12 months and at the conclusion of the study. Peripheral blood samples were analysed for total IgE, eosinophil count and cytokine profiles in order to understand immunological shifts associated with AIT. All laboratory protocols followed standardised procedures, and stringent quality control was used to ensure reliability and reproducibility. Continuous monitoring of adherence was included, which is important as incomplete or irregular dosing can have a major impact on outcomes [9].

Statistical techniques included descriptive and inferential statistics. Continuous variables, such as indices of lung function and immunological markers, were compared with paired or independent t tests and categorical variables, such as incidence of adverse events, were compared with chi-square tests. A threshold of significance of $p < 0.05$ was used. Ethical approval was obtained from the Tashkent State Medical University Ethics Committee, and informed consent was obtained from parents or the legal guardians of all the participants. The methodological framework, therefore, enabled a thorough evaluation of the efficacy as well as safety of AIT in a real-life paediatric population, taking into consideration the individual differences of allergic sensitivity, severity of disease and adherence to treatment.

3. Results and Discussion

Clinical and immunological results of children undergoing AIT were systematically recorded during the observation period and compared with those of the control group who received standard therapy only. Baseline comparability in age, asthma severity, symptom frequency and pulmonary function parameters ensured that any differences that were found could be ascribed to the therapeutic effect of immunotherapy. Over the duration of the treatment, AIT recipients showed a gradual reduction in the scores of asthma symptoms, with significant improvements already occurring as early as six months. By the end of the study, most participants reported significant reductions in both daytime and night-time symptoms, including coughing, wheezing and dyspnoea - the sign of improved disease control and a better quality of life.

These results were supported by pulmonary function tests. Significant improvements in mean FEV1 and PEFr values were noted in the AIT group when compared to baseline results, whereas the control group showed moderate improvements due mostly to standard pharmacotherapy. Consequently, AIT not only supplemented conventional therapy but also induced prolonged physiological improvement of airway function [10].

Immunological analyses showed some interesting trends: the children receiving AIT showed a gradual decrease in total IgE concentrations and peripheral eosinophil counts with favourable changes on cytokines profiles indicative of a more regulated immunological response. These changes are consistent with the expected immunomodulatory effects of AIT, and of reduced hypersensitivity to specific allergens and induction of tolerance. Conversely, the control group was able to maintain fairly stable immunological parameters, which underscores the unique role of AIT in allowing alteration of disease trajectory in addition to symptomatic relief.

Safety evaluations showed that AIT was usually well tolerated. Most of the adverse reactions were mild in nature and were transient, including local reactions (e.g., redness, swelling, itching) at the injection or sublingual administration site. Systemic reactions were rare and confined to mild episodes of transient rhinitis or mild wheezing, all of which were treated successfully without even the need for hospitalisation. No severe anaphylactic reactions were documented, and treatment cessation due to adverse events was rare, favouring the good safety profile of AIT when given under appropriate clinical supervision [12].

Data from parental reports and symptom diaries strengthened clinical and immunological data. Children receiving AIT had fewer medications added, less

exacerbation and better exercise tolerance and engagement in daily activities. Families also reported greater confidence in disease management and less anxiety for asthma attacks. Collectively, these outcomes describe how AIT provides not only measurable physiological benefits, but also social or psychosocial advantages for children and their caregivers [12].

In conclusion, the study shows allergen-specific immunotherapy in paediatric asthma to be associated with important improvements in symptom control, pulmonary function and immunological parameters with a low incidence of adverse events. These findings offer impressive evidence for the inclusion of AIT as an effective and safe adjunct to traditional asthma management in paediatric populations that gives weight to its potential for achieving long-term disease modification and improving quality of life.

Discussion

The current investigation provides strong evidence that allergen-specific immunotherapy (AIT) has important benefits for paediatric patients with asthma, as shown by both clinical and immunological modulation. A progressive decrease in asthma symptom scores in the participants supports the ability of AIT to bring about meaningful improvements in daily functioning and quality of life. Children participating in immunotherapy experienced less daytime and nighttime symptoms, less utilisation of rescue medication and improved tolerance to physical activity - all of which are important markers of good asthma control [13]. These findings align with the growing body of literature that supports AIT as a disease-modifying intervention that is able to influence the underlying immune dysregulation and not only the symptoms.

Data regarding lung function obtained from this study gives further proof of the physiological effect of AIT. Increased FEV1 and PEF values suggest an improvement in the level of airway patency and reduced bronchial hyperresponsiveness, results which are in accordance with previous trials in children showing sustained respiratory improvements after long-term exposure to allergen under controlled immunotherapy procedures [14]. In contrast, the control group showed only modest improvements, and this demonstrates the limited effectiveness of pharmacological therapy alone in achieving comprehensive asthma management. These observations support the premise that the incorporation of AIT in standard treatment regimens can have an additive or synergistic effect to improve both clinical and functional outcomes.

In an immunological way, the study confirms that AIT provokes strong modulation of the immunological system. Changes in total IgE and peripheral eosinophil numbers and beneficial changes in cytokine profiles support the hypothesis that immunotherapy induces tolerance to specific allergens. These results support the conceptual framework of allergen-specific immunotherapy, which focuses on the induction of regulatory T cell responses and inhibition of Th2-mediated hypersensitivity [15]. Such immunological changes are critical not only for short-term relief of symptoms but also for the long-term prevention of disease progression, including the development of other allergic comorbidities such as allergic rhinitis and atopic dermatitis.

Safety forms a major part of the thinking process in paediatric immunotherapy, and the current results have confirmed that AIT is generally well tolerated. The majority of the adverse events were mild and localised with either injection-site reaction or oral pruritus, while systemic reactions were rare and controllable. Crucially, no severe anaphylactic events were detected, and this emphasises the fact that, with appropriate medical supervision and patient selection, AIT can be safely administered to children [16]. The close monitoring of adherence and adverse events throughout the trial process also highlights the importance of structured clinical oversight to guarantee efficacy as well as safety.

Furthermore, the psychosocial effect of AIT must not be underrated. Parents and caregivers reported reduced anxiety about asthma exacerbations, increased confidence in

how to manage the disease and more participation of children in educational and recreational activities. These findings suggest more global implications of immunotherapy beyond physiologic improvement, with successful therapy able to have positive effects on the family dynamic, the child and the overall well-being.

Taken together, this study supports the proposition that allergen-specific immunotherapy is a valuable adjunct to traditional asthma management in children. By treating both the clinical manifestations of the disease and the immunological basis of the disease, AIT is a comprehensive disease approach that enhances symptom control, lung function, immunological tolerance and quality of life. The evidence further suggests that incorporating AIT in personalising the treatment plan can optimise the outcome and potentially attenuate the long-term burden of Pediatric asthma. These results call for broader consideration of immunotherapy in routine paediatric practice, as long as appropriate safety measures, patient selection, and follow-up protocols are maintained.

4. Conclusion

The study highlights that allergen-specific immunotherapy (AIT) is an effective and safe strategy for dealing with paediatric asthma. Children receiving AIT had significant reductions in both daytime and nighttime symptoms, a reduction in exacerbations and a reduction in the use of rescue medications. Lung function measures such as FEV1 and PEFr both showed consistent improvement, suggesting improvement in airway control beyond conservative therapy. Immunological studies showed the reduction of IgE and eosinophil mucosal concentrations, showing the ability of the therapy to control the immune response and tolerance to certain allergens. Safety outcomes were favourable, and most of the adverse events were mild and transient, and there were no severe systemic reactions, confirming that AIT is well-tolerated under the right supervision. Apart from clinical and physiological improvements, the therapy had a positive impact on the psychosocial aspects, improving children's participation in daily activities and parental confidence in the management of asthma. In conclusion, AIT is an all-round strategy when it comes to the care for asthma in children. By addressing both the underlying immune mechanisms and the clinical symptoms, it promotes long-term control of the disease, enhances quality of life and complements the conventional treatments, thus calling for widespread incorporation of immunotherapy in the personalised management plan for paediatric asthma.

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