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SCIT or SLIT for pollen allergy?

Real-World data speak for subcutaneous immunotherapy (SCIT)

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Allergen immunotherapy (AIT) is presently the only causal therapy for immunoglobulin (Ig)E-mediated allergic diseases, provided that it is implemented continuously for at least 3 years. Whether it is successful depends substantially on patient adherence, which in turn is closely tied to the method of administration. In the case of pollen allergy there are two different therapeutic options: subcutaneous (SCIT) and sublingual (SLIT) immunotherapy. A current analysis of real-world data collected over a long term has shown that, with a view to long-term effects and adherence, SCIT has advantages compared with SLIT.

Real-world data support physicians in private practice in making therapy decisions and are becoming increasingly important. They supplement randomized clinical studies, which are still unquestionably the gold standard of evidence-based medicine: Speaking in favor of randomized trials are the inclusion of a specific, defined patient population under controlled, standardized conditions; the double-blind and placebo-controlled implementation; and the thereby valid assessment of efficacy and safety. Real-world data, on the other hand, are based on very large numbers of patients and have very high statistical significance. Unlike clinical trials, subpopulations are also taken into consideration, i.e., the reality of practice is represented, so that the severity of the disease is included and, for example, patients with rhinitis plus asthma or polyallergics can be analyzed separately. Also of value for the choice of a therapy are statements about adherence in everyday practice and long-term data. Because up to now there has been a lack of reliable data from daily practice, the European Academy of Allergy and Clinical Immunology (EAACI) initiated a systematic review of observational studies on allergen immunotherapy (AIT). In the interest of better patient care, therefore, the expert association calls for more AIT registries, for example, that generate strong evidence on the basis of standardized protocols and facilitate treatment decisions in everyday clinical practice [1].

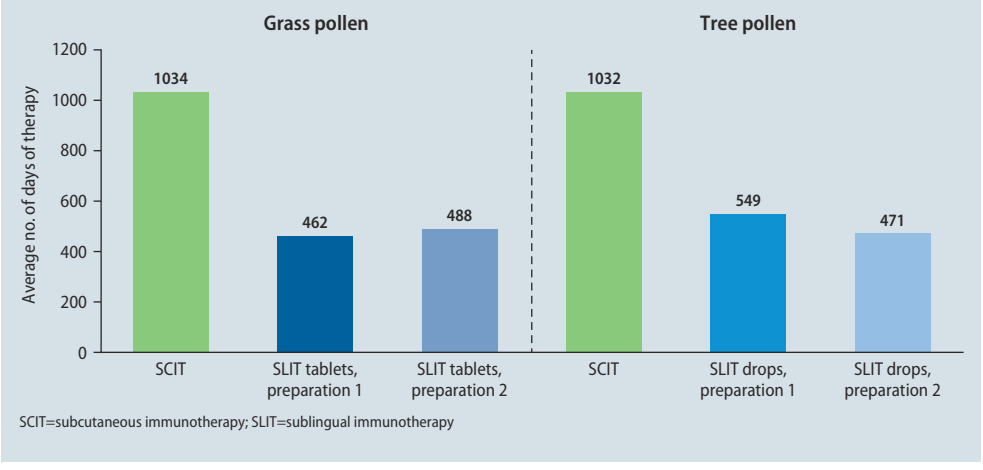

Fig. 1 Statistical evaluation, average number of days of therapy (DOT) for perennial SCIT versus SLIT tablets for grass and tree pollen allergy sufferers (mod. from [6])

AIT is the therapy of choice

Allergic rhinitis (AR) has been on the rise for years [2], sharply reduces the quality of life of those affected, and is, moreover, connected with an increased risk for the development of allergic asthma [3]. The therapy of choice for AR and allergic asthma is AIT, the only one of the available options that can modify and possibly effect a remission of the symptoms for several years without further AIT – provided that it is carried out for at least 3 years [4,5]. The success of the therapy is therefore directly linked to the patients' adherence. There are two possible options for the therapy: subcutaneous (SCIT, e.g. with Allergovit®) and sublingual (SLIT) immunotherapy. The SCIT injection is normally reserved for the physician. Particularly during the induction phase, therefore, regular visits to the doctor and monitoring following the injection are necessary. However, following a first briefing, SLIT can be taken by the affected themselves at home. At

first glance, that might be preferred by many patients. However, to what extent they really use the therapy as regularly as would be necessary for its success remains an open question. Real-world data can show how it really is with adherence to SCIT and SLIT. A current study pursued this question with people affected by grass and tree pollen induced AR and asthma [6].

Long-term data analysis speaks in favor of SCIT

Data from the IMS LRx® Databank (IQVIA, Frankfurt a.M.) were included in the cohort analysis. The data collection (done according to guidelines of the Federal Data Protection Act) involved prescription data from German pharmacies, including ca. 60 % of all social health insurance prescriptions, i.e., representing a pool of >40 million patients. The analysis period covered the years 2008 to 2017; the follow-up was up to 6 years, and the medication was allocated via the "Pharmazentralnummer" (PZN). For the analysis, people afflicted with AR or asthma with AIT were compared by matching with those who had received only symptomatic AR or asthma therapies. Study endpoints were adherence to therapy, progression of AR, and progression of allergic asthma. The effects of SCIT or SLIT were determined by means of multivariate regression analysis after adjusting for confounding factors such as demographics and prescription.

Better adherence with SCIT

The evaluation showed clear advantages for SCIT with a view to adherence. For both investigated pollen types, the adherence was better with SCIT than with SLIT in the first 2 years of therapy: For grass and tree pollen, after 2 years 60.1–61.8 % adherence was realized with SCIT and 29.5–36.5 % adherence with SLIT. A comparison of different age-groups showed the highest adherence to SCIT among children, followed by adolescents and adults. In contrast, the adherence to SLIT was worse with adolescents than with adults. These results were also confirmed by the analysis of the days of therapy (DOT) for the SCIT group, who were more than twice as long in therapy as the SLIT group (**Fig. 1**) [6]. This result leads to the conclusion that SCIT with Allergovit® for grass and cereal pollen and Allergovit® for tree pollen is easier and ultimately more effective in terms of adherence.

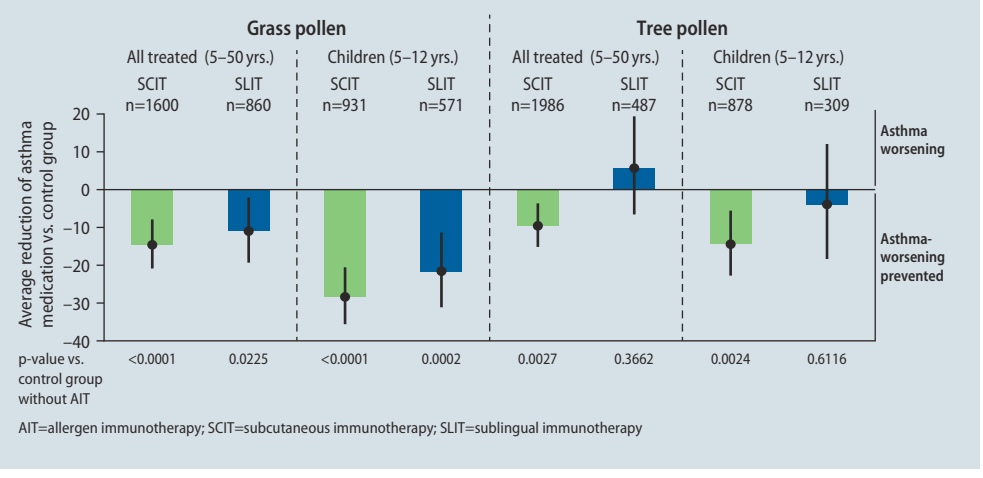

Fig. 2 Reduction of medication in the follow-up period after SCIT and SLIT (grass and tree pollen products) compared with the control group (mod. from [6])

SCIT: Prevention of worsening of AR and allergic asthma

To what extent the patients considered in the analysis profited from the respective AIT was shown by the acceptance of the symptom-relieving medications in the respective groups, whereby SCIT was superior across all groups. Both options reduced the need for medication for AR. With SCIT (using Allergovit® for grass and cereal pollen) even a −64.8 % reduction of the symptomatic rhinitis medication was observed. But the asthma medication was also significantly reduced during follow-up after SCIT, whereas it even increased with the tree pollen SLIT (**Fig. 2**) [6].

Real-world data become increasingly important

Clinical studies are unsuitable for determining the benefits of medications in practice. Regulatory authorities (European Medicines Agency [EMA] and the Food and Drug Administration [FDA]) and payers have meanwhile realized that real-world data are indispensable here, and they are increasingly interested in supplementing the evidence from clinical studies with real-world evidence in order to improve patient care. Following this trend, this long-term data analysis has also been included in the recently published guideline on AIT of Germany, Austria and Switzerland [7].

References
1. Paoletti G et al., Allergy 2021Sep, 76:2663–2672
2. Goksor E et al., Eur Res J 2018, 52 Supp1
3. Ozdoganoglu T et al., Ther Adv Respir Dis 2012, 6:25–39
4. Roberts G et al., Allergy 2018, 73:765–798
5. Halken S et al., Pediatr Allergy Immunol 2017, 28:728–745
6. Vogelberg Ch et al., Patient Prefer Adherence 2020, 14:817–827
7. Pfaar O et al., Allergol Select 2022, 6:167–232

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Allergovit® Pollen preparation

Composition: Chemically modified allergen extracts (allergoids) from pollen for allergen immunotherapy / hyposensitization, adsorbed to aluminium hydroxide, preserved with phenol and suspended in physiological saline solution with sodium hydrogen carbonate; water for injection. Standardization is indicated in TU (therapeutic units). Strength A: 1,000 TU/mL; strength B: 10,000 TU/mL.

Indications: Causal treatment of allergic (IgE-mediated) diseases, such as allergic rhinitis, allergic conjunctivitis, allergic bronchial asthma etc., triggered by exposure to unavoidable allergens.

Contraindications: Hypersensitivity to any of the excipients, uncontrolled asthma, irreversible changes in the reaction organ, inflammatory/febrile diseases, severe acute or chronic diseases (e.g. malignant diseases, active tuberculosis), clinically significant cardiovascular insufficiency - in cardiovascular diseases, there is an increased risk of adverse reactions to adrenaline, treatment with beta-blockers (local, systemic), diseases of the immune system (autoimmune diseases, immune complex-induced immunopathies, immunodeficiencies, multiple sclerosis etc.), severe mental disorders.

Side effects: Local and/or systemic reactions (up to anaphylactic shock) must be expected, then stop injection immediately. Hypersensitivity; anaphylactic reaction; anaphylactic shock; drug intolerance; conjunctival oedema; conjunctival disorder; conjunctivitis (allergic); eye pruritus; eye irritation; mydriasis; visual impairment; conjunctival hyperaemia; ocular hyperaemia; swelling of eyelid; eyelid oedema; face oedema; angioedema; oral pruritus; swollen tongue; lip swelling; laryngeal oedema; glossodynia; dysphagia; gastrointestinal disorder; abdominal pain; nausea; diarrhoea; vomiting; increased appetite; weight increased; salivary hypersecretion; at the injection site: erythema, pruritus, swelling, pain, discolouration, reaction, rash, urticaria, warmth, discomfort, eczema, erosion, granuloma, nodule, haematoma, haemorrhage, hypersensitivity, hypoaesthesia, induration, oedema, vesicles, cellulitis, paraesthesia, scar; local reaction; malaise; asthenia; discomfort; paraesthesia; inflammation; pyrexia; feeling hot; feeling of body temperature change; chills; hyperhidrosis; headache; migraine; dizziness; vertigo; tachycardia; palpitations; chest discomfort; loss of consciousness; syncope; cold sweat; anxiety; restlessness; tiredness; somnolence; insomnia; sensation of foreign body; flushing; burning sensation; tremor; pain; flank pain; pain in extremity; arthralgia; swelling; peripheral swelling; oedema peripheral; nasopharyngitis; rhinitis (allergic); nasal pruritus; nasal congestion; oropharyngeal pain; rhinorrhoea; increased upper airway secretion; asthma; asthmatic crisis; bronchospasm; tachypnoea; respiratory distress; cough; pseudocroup; dyspnoea; cyanosis; sneezing; throat irritation; throat tightness; stridor; wheezing; forced expiratory volume decreased; peak expiratory flow rate decreased; blood pressure diastolic increased; blood pressure systolic increased; blood pressure decreased; orthostatic hypotension; urinary incontinence; dermatitis atopic; dermatitis allergic; neurodermatitis; scleroderma; (generalized) erythema; granuloma skin; blister; pruritus (generalized); rash (generalized); urticaria (chronic); eczema; haematoma; lymphoedema. When using the dosage scheme with an accelerated dose increase (4 injections, only for adults, grass and cereal pollen and tree pollen), side effects can occur more frequently than with the escalation treatment according to the standard scheme. The side effects mostly only appear 30 minutes after the injection. The systemic reactions are mild and not more pronounced in severity than in the standard scheme. When using the one-strength dose escalation scheme (3 injections, only for grass and cereal pollen), side effects can occur more frequently than when using the standard scheme. In addition, these occur at an earlier time in the dose escalation phase compared to the standard scheme. The severity of the systemic reactions is not more pronounced than in the standard scheme.

For additional information on doses, administration etc. see package insert. The general classification for supply depends on local requirements.

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