

SHORT REPORT

Randomized open comparison of the safety of SLIT in a no-updosing and traditional updosing schedule in patients with Parietaria allergy

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ABSTRACT

Background: Due to optimal safety of sublingual immunotherapy (SLIT), it was suggested that a slow up-dosing phase maybe not necessary, and therefore the treatment will be more patient-friendly, avoiding dosing mistakes.

Patients: Twenty adult patients suffering allergic rhinitis due to Parietaria, were enrolled. Half of them received the traditional schedule and the other half immediately started with 200 STU.

Results: No difference was observed between the traditional up-dosing treatment schedule and no-updosing treatment schedule in terms of side effects, even mild local side effects was grater with traditional regimen.

Key word: Sublingual immunotherapy. Steady-dose. Safety.

Sublingual immunotherapy (SLIT) is now recognized as a viable alternative to the injection route¹.

Due to the optimal safety, and the absence of systemic severe side effects, it was suggested that a slow up-dosing phase maybe not necessary, and recent trials showed that starting the SLIT course with the maintenance dose does not lead to remarkable increase in side effects². Omitting the updosing phase, which requires the use of different vials of the product, is expected to make the treatment more patient-friendly and to avoid dosing mistakes. Based on this background we performed an exploratory study to compare the safety of the traditional and no-updosing schedules in allergic patients.

Consecutive adult outpatients suffering from intermittent or persistent allergic rhinitis (with/without mild asthma) due to Parietaria, and fulfilling the criteria for prescribing immunotherapy³, were enrolled. Sensitization to Parietaria was confirmed by skin prick test and/or RAST assay, and the symptoms had to have been present for at least two years. Patients were randomized, according to a computer-generated list, to receive either the traditional build-up or a steady dosage schedule (starting with the maintenance dose). SLITone® (ALK-Abelló, Lainate, Milan) was started about two months before the pollen season. The traditional schedule involved an updosing phase where the maintenance dose of 200 Standard Therapeutic Units (STU) was reached in about 15 days. In the no-updosing group, patients immediately started with 200 STU. SLITone® was given once daily for three months, cumulating a dosage of 85-90 mcg Par j 1. All patients were required to report on a structured diary card any adverse event occurring at each dose. Adverse events were subdivided into local (oral itching/ swelling) and systemic (urticaria, asthma, rhinitis, gastrointestinal com-

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plaints, anaphylaxis) and graded as mild (no need for treatment or dose adjusting), moderate (need for drugs/medical advice or dose adjusting or SLITone® discontinuation), and severe (life-threatening or hospitalization or emergency care needed)⁴. Skin tests, CAP-RAST and methacholine challenge were evaluated before starting SLITone® and after 3 months (in pollen season). Patients also had to rate the tolerability of SLITone® on a visual analog scale (0 worst to 10 best) at the end of the treatment course.

Twenty patients were enrolled (11 men, 9 women, age range 18-45 years). We observed mild oral itching in one patient in the no-updosing group and in 8 patients in the traditional updosing group. In no case was SLITone® discontinued or dose adjusted. In the patient on no-updosing schedule, side effects disappeared within the first week, whereas in the traditional build-up group they persisted for about 15 days. The tolerability on the VAS was rated by patients 9.6/10 and 9.1/10 respectively. No change in the CAP-RAST and skin test positivity at the end of SLIT was found in the two groups versus baseline values. The methacholine PD20 provocation dose at the beginning (out-season) and end (in-season) of treatment was 670.2 vs 685 mcg in the updosing group and 741.2 VS 836.5 in the no-updosing (non-significant), respectively.

This exploratory observational study performed in an open way showed that no difference exists between the traditional up-dosing treatment schedule and no-updosing treatment schedule in terms of side effects. This is in accordance with a recent review⁵. Noticeably, the occurrence of mild local side effects was even greater with the traditional regimen. SLIT seemed also to prevent the usually observed increase in bronchial reactivity during the pollen season. Based on this result, we speculate that future double blind placebo controlled trials could be conducted with no-updosing schedule, which is easier to manage.

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