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Safety of sublingual immunotherapy with a monomeric allergoid in very young children

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Sublingual immunotherapy (SLIT) is approved by official documents (1), nevertheless some concerns still remain about its use in children. The age below 5 years is considered a relative contraindication (1), as severe side effects are more difficult to treat. SLIT is devoid of relevant risks as testified by 20 years of use and of controlled trials, and in everyday clinical practice it seems to be safe in very young children also, but a systematic assessment is still to be carried out.

Sublingual immunotherapy is safe in very young children.

We performed a safety survey of SLIT in children under the age of 5 years. They suffered from intermittent or mild persistent asthma or persistent rhinitis (2), and had positive skin-prick test for at least one of the following: dust mites, grasses, parietaria, olive, birch, cat and dog dander. The SLIT was a monomeric allergoid, standardized in Allergy Units (LAIS®; Lofarma S.p.A., Milan, Italy), prepared as aqueous drops. After a 3-week build-up, a maintenance of 4 drops/day of the maximum concentration (3000 AU/ml) was given continuously. The administration was by oral means. The first doses were given at the pediatrician's office. Parents were carefully instructed on how to administer SLIT, and a physician was always available for telephonic contact.

Parents had to fill a diary card at each dose. Side effects were subdivided into: eye symptoms, rhinitis, asthma, gastrointestinal (nausea, vomiting, abdominal pain), urticaria, angioedema, anaphylaxis. The severity was graded as: low (no treatment/dose adjusting), moderate (need for drugs/medical advice/discontinuation), and severe (life-threatening/hospitalization/emergency care) (3). Mild transient oral itching requiring no intervention was not considered. At the end of the treatment, the parents indicated if symptoms had worsened, improved or not changed. All parents gave their consent and the study was approved by the Ethical Committee.

Thirty-six children (33 males), aged between 1 year 11 months and 3 years 10 months (mean 3 years 2 months) were enrolled: 17 had persistent asthma, 12 intermittent asthma and 33 rhinoconjunctivitis. Nineteen patients received mite-SLIT and 17 grass-SLIT. The mean follow-up was 22.2 months (1–3 years), and the number of doses was about 25 200. One episode of abdominal pain occurred in two children (5% of patients; 0.071 per 1000 doses) during the maintenance phase. One episode was mild and transient (< 30 min) and one was moderate, requiring a temporary adjustment of the dose. In this latter case, the maximum maintenance dose was reached after few days without problems. In 30 of the 36 children, the omitted doses were < 10/year (85%). The most frequent reasons for skipping doses wereaccidental omission and febrile episodes. The evaluation by parents was: highly improved in 21 children, moderately improved in nine, slightly improved in four and unchanged in two.

Allergen immunotherapy is the only treatment capable of modifying the natural history of allergy (4, 5), and it is reasonable to expect that, when used as early as possible, the clinical outcome is more favorable. In our survey, the number of patients is small, and rare events could not be detected; nevertheless, the data were obtained by a rigorous follow-up in a real-life setting. Thus, the present observation suggests that SLIT could also be safely administered to very young children.

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