

Effect of omalizumab in health care workers with occupational latex allergy

To the Editor:

Latex allergy is common among health care workers who are frequently exposed to latex gloves and other latex-containing medical supplies.¹ Product avoidance is difficult to achieve for many health care workers, and other management options are limited. Type I hypersensitivity reactions, such as latex allergy, are known to be mediated by IgE, and targeting IgE has already been investigated in the treatment of other allergic disorders. Omalizumab, a recombinant and humanized mAb, has been shown to be clinically efficacious in the treatment of patients with allergic asthma² and rhinitis.³ On the basis of such findings, we have conducted a double-blind, randomized, placebo-controlled study to determine whether the benefits of anti-IgE therapy extend to those with latex allergy. The study population was 18 health care workers (15 female and 3 male patients; mean age, 40 years) who had clinical symptoms of occupational latex allergy for at least 1 year (rhinitis, conjunctivitis, and/or mild-to-moderate asthma) and who had positive skin prick test responses to 2 preparations of latex allergens and relevant serum specific IgE levels (RAST class ≥ 2). Further inclusion criteria included a positive conjunctival challenge test total score (range, 0-13; positive if ≥ 7)⁴ and increased total IgE levels (30-700 IU/mL). Subjects were randomly treated with either omalizumab ($n = 9$) or placebo ($n = 9$) administered by means of subcutaneous injection every 2 or 4 weeks for 16 weeks, during which time no change in the occupational environment was permitted. The dose of omalizumab was 150 to 750 mg/mo, depending on body weight and total serum IgE level at baseline. Efficacy was primarily evaluated in terms of the conjunctival challenge test total score after 8 and 16 weeks' treatment, along with skin reactivity to 3 dilutions of latex allergens and to latex glove exposure at study end (responders only). The conjunctival allergen challenge is a validated model developed by Abelson et al,⁴ and it has already been used in a previous study on latex allergy.⁵ The total conjunctival score was the sum

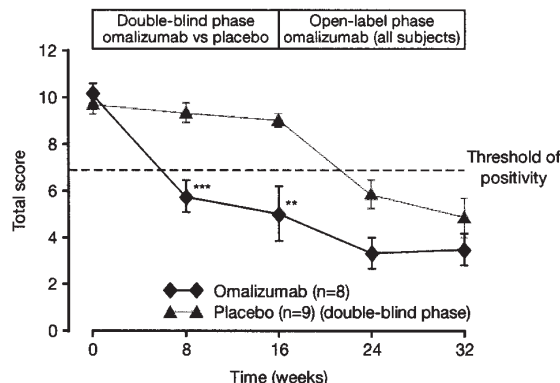


FIG 1. Mean ($\pm$ SEM) total score of the conjunctival challenge test during double-blind treatment with omalizumab or placebo, followed by open-label treatment with omalizumab (all subjects), for latex allergy in health care workers. ** $P < .01$ and *** $P < .001$ versus placebo (Wilcoxon rank sum test).

of 5 subscores: redness, eyelid swelling, chemosis, and tearing, which were graded by the investigator from 0 to 3 (0, absent; 1, mild; 2, moderate; and 3, severe), and itching, which was graded by the patient from 0 to 4 (0, absent; 1, mild; 2, moderate; 3, severe; and 4, incapacitating). A clinically relevant change in the conjunctival score was defined as a decrease from an abnormal score (>7) to a normal score (<7). The use of rescue medication (oral or ocular antihistamines; oral, nasal or inhaled corticosteroids; and inhaled salbutamol) was permitted on an as-needed basis to control symptoms.

Among the 16 evaluable subjects (2 patients of the omalizumab group discontinued: one for administrative problems and one for an adverse event), the mean conjunctival challenge test total score decreased from 10.0 to 5.0 during omalizumab therapy, whereas scores remained unchanged (from 9.67 to 9.0) for placebo recipients ($P = .003$, Wilcoxon rank sum test; Fig 1). This difference remained significant when the analysis accounts for the 2 premature discontinuations with the last total score carried forward (omalizumab, -4.33 ; placebo, -0.67 ; $P = .006$). After 16 weeks, scores were negative in 4 (57.1%) of 7 subjects treated with omalizumab compared with none of the 9 placebo-treated subjects ($P = .019$, Fisher exact test). Improvements in conjunctival challenge test scores with omalizumab were apparent for all subscores, including redness, chemosis, tears, and itching, whereas no relevant changes were apparent for placebo recipients. All subjects were subsequently treated with open-label omalizumab for a further 16 weeks. Some 8 (88.9%) of 9 subjects previously treated with placebo subsequently achieved negative total scores on the conjunctival challenge test along with the 3 remaining omalizumab-treated subjects who had positive scores after the first 16 weeks of treatment. The overall ocular response rate was therefore 93.8% (15/16), with 11 of 15 subjects also having a negative response on study completion to a latex glove challenge test (mild response in 4/15 subjects). At study end, the patients treat-

ed with omalizumab for 32 weeks exhibited mean relative decreases in skin reaction to the dilutions 11, 33, and 100 IR of latex allergens of 61%, 49%, and 64%, respectively. The 2 treatment groups had similar exposure to latex allergens during the study. Tolerability of omalizumab was good, with only 2 reports of related injection-site reactions during double-blind treatment (1 patient with 3 episodes of injection-site pain of increasing severity leading to the withdrawal of the subject and 1 patient with 2 short episodes of injection-site pruritus) and no clinically relevant changes in laboratory parameters.

In summary, the findings of this study show that omalizumab has clinically relevant ocular and skin antiallergic activity in health care workers with occupational latex allergy. Further long-term studies are clearly warranted in patients with latex allergy.

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