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Omalizumab's Effectiveness and Safety in Treating Adult Patients with Exercise-Induced Anaphylaxis caused by Wheat: decrease of in Vitro Basophil Activation and Allergic Reactivity to Wheat

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Abstract

Anaphylactic shock usually occurs in people with wheat-dependent exercise-induced anaphylaxis (WDEIA), hence avoiding wheat products is advised. For adult patients with WDEIA, our goal was to assess the effectiveness and safety of long-term omalizumab treatment. 20 adult WDEIA patients were enrolled in this phase 2, multicenter, single-arm experiment (UMIN 000019250). Every patient received 150-600 mg of omalizumab subcutaneously, and during the administration period (0-48 weeks) and observation period, assessments (basophil activation and blood testing) were carried out at regular intervals (48–68 weeks). The proportion of patients who reached a basophil activation rate of less than 10% with fractionated wheat preparations served as the primary endpoint, while the proportion of patients who experienced no allergic reactions after consuming wheat products served as the secondary endpoint.

Keywords: Omalizumab; Allergic reaction; Anaphylaxis

Introduction

Food-dependent exercise-induced anaphylaxis (FDEIA) is a subtype of IgE-mediated food allergies in which in addition to consuming the offending foods, exercise or other secondary causes can also trigger allergic symptoms. 1 More than 60% of the meals that cause FDEIA in adults are made of wheat. Anaphylactic shock is a common occurrence in FDEIA patients, hence avoiding the offending foods is typically advised in these situations. There isn't a proven effective treatment for FDEIA at the moment **[1-3]**.

Methods

Six locations in Japan—Shimane University Hospital, Hiroshima University Hospital, Kobe University Hospital, Tokyo Medical and Dental University Hospital, Hyogo Prefectural Kakogawa Medical Center, and Okabe Allergy Clinic—completed a phase 2, multicentre single-arm trial. The participants with WDEIA either met the diagnostic criteria established by the Health Labor Sciences Research Grant research group or the Special Committee for the Safety of Protein Hydrolysate in Cosmetics5 (diagnosis of HWP-WDEIA was granted) (diagnosis of CO-WDEIA was given) more than 20 years old; avoiding wheat products due to a history of anaphylaxis following wheat intake within a year; or having positive results from an IgE test performed during the last four weeks against wheat and/or gluten **[4-8]**.

At the time of enrollment, we received participants' written informed permission. The study received clearance from Shimane University's ethical committee and the dean of the faculty of medicine (approval number 1945), and it was preregistered with a public registry (UMIN 000019250).

Omalizumab administration dosage

According to the prescribed administration protocol for omalizumab for bronchial asthma, the patients received 150-600 mg of omalizumab (Xolair®, Novartis Pharma, Tokyo, Japan) by subcutaneous administration 12 times at four-week intervals or 24 times at two-week intervals (Supplementary Table 2). During the course of omalizumab treatment, assessments (BAT and blood examination) were carried out at regular intervals (0, 12, 20, 28, 36, and 44 weeks), and they were followed up with routine observations (at 48, 52, 56, 60, 64, and 68 weeks) **[9]**.

Test for basophil activation

Using peripheral blood basophils, a basophil activation test (BAT) based on allergen-induced CD203c expression was carried out.

7, 8, 9 HWP (final concentrations of 0.1 and 1 g/mL), PBS soluble fraction of wheat protein (final concentrations of 1 and 10 g/mL), ethanol extraction fraction of wheat protein (final concentrations of 1 and 10 g/mL), alkali extraction fraction of wheat protein (final concentrations of 1 and 10 g/mL), and purified -5 gliadin (final concentrations of 0.1 and 1 g/mL) were the activation agents Fluorescence-activated cell sorting was used to track CD203c expression on the basophil surface following activation with these substances **[10]**. The final figure was represented as a percentage of the activation rate after comparison with anti-IgE activation.

Discussion

Malizumab was demonstrated to be secure and efficient for adult patients with WDEIA in the primary endpoint and the secondary endpoint of this single-arm open study of long-term omalizumab medication. The percentage of patients who attained an activation rate below 10% in CD203c expression-based BAT, an objective metric to assess sensitization circumstances in IgE-mediated allergy, served as the primary outcome. Based on our earlier discovery that patients with wheat allergy had activation rates more than 10% on CD203c expression-based BAT, but patients who were tolerant to wheat displayed activation rates lower than 10%, the activation rate was set to be less than 10%. 9 Moreover, during CD203c expression-based BAT, patients with HWP-WDEIA and CO-WDEIA showed different

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reaction patterns. This outcome is very consistent with what we had previously noticed. This outcome is consistent with our earlier finding that CO-WDEIA patients primarily reacted to pure -5 gliadin but not to HWP, whereas HWP-WDEIA patients largely reacted to HWP.

Conclusion

Since more than 80% of the patients achieved basophil activation below 10% with all four wheat preparations in the present study, it was clear that the present long-term open study had a greater inhibitory effect on basophil activation with wheat preparations than our previous pilot study using short-term 150 mg fixed dose omalizumab. These findings suggest that the dose and duration of omalizumab treatment are crucial elements for obtaining effective basophil/mast cell suppression of wheat allergen sensitization. Also, the current study showed that omalizumab is effective for treating HWP-WDEIA, which involves sensitised percutaneous and/or rhino-conjunctival pathways, and CO-WDEIA, which is thought to include sensitization through the gastrointestinal system. The lack of an omalizumab randomised placebo-controlled study and the small number of patients included are two drawbacks of our current investigation.

In conclusion, this study shows the effectiveness and safety of omalizumab when administered in accordance with the administration guidelines for Xolair for bronchial asthma. It also offers important information on the treatment of adult patients with WDEIA who avoid eating wheat.

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