Omalizumab combined with oral immunotherapy for the treatment of severe cow's milk allergy: our 2-year-long experience

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Background: Oral immunotherapy (OIT) combined with omalizumab (O) can be an effective and safe approach treatment to rapid desensitization in children with severe cow's milk allergy (CMA). We report our experience.

Objective: To evaluate the safety and efficacy of OIT combined with O.

Methods: Volunteers with severe CMA that had previously interrupted a conventional OIT because of dose-related severe anaphylactic reactions were enrolled. Informed written consent was obtained by the respective parents before the treatment. As off-label treatment, O was administered according to the package insert for asthma treatment. Each pts undertook s.c. injections of O for 8 wks prior to and 8 wks following the initiation of OIT. On the initial escalation day, dosing began at 1.5 ml of cow’s milk (CM, 5 mg of proteins) and were slowly increased until the pt reached a final dose of 200 ml or if any adverse event (AEs). The highest tolerated dose (i.e. with no clinical reactivity) determined the pt’s starting daily home dose. The pts returned to the clinic every 2 wks for a dose escalation visit. OIT protocol did not advance according to a fixed calendar, but, rather were individualized according to pts’ allergic reactions and safety outcomes. After the up-dosing regimen the maintenance phase was performed (200 ml of CM daily and dairy products ad libitum).

Results: We have enrolled 6 children (n male = 4 ), aged 9.8 ± 2.31 yrs (mean ± SD) suffering from severe CMA. 4 children had concomitant allergic asthma (A) and one of the latter atopic dermatitis, too.

Efficacy: 2 pts reached the maintenance dose of CM 200 ml after 17 wks; 1 reached the dose of 150 ml of CM and dairy products after 7 months. All of them are going on daily maintenance intake since a 12 months.

3 pts interrupted OIT during the build-up phase: 1 for severe AE (2 ml CM); 1 for concomitant severe A; 1 for personal problem.

Safety: 2 pts developed severe anaphylactic reactions after dose intake: 1 at the increasing dose of 2ml [rhinitis (R), cough, A, angioedema-urticaria (U), hypotension]; 1 at the maintenance dose of 150 ml (U&A). All of them have history of A.

The same 2 pts developed mild AEs during the induction phase of OIT: 1 reacted at the 8 ml dose (R) and 25 mL dose of CM (U); another at 150 ml of CM (R & U).

Discussion and Conclusions: This combined approach could allow for a more successful and safer desensitization in children with high-risk CMA that had failed a conventional OIT protocol. However, in pts with concomitant A, it could be less effective.