

RESEARCH ARTICLE

A Clinical and Immuno-Allergological Study of the Efficacy of Enterosgel in Food Allergy

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Abstract

This article demonstrates the clinical efficacy of Enterosgel in the treatment of food allergy. Enterosgel was shown to have beneficial effect on the allergy status and promote normalization of total serum IgE levels, early interferon, and pro-allergic cytokine (interleukin-5) concentrations in patients with food allergy manifesting by angioedema. The reported studies the benefits of gastrointestinal sorption (enterosorption) achieved with Enterosgel during the combination treatment in patients with food allergy manifesting by angioedema.

Keywords: adsorbent, angioedema, circulating immune complexes, food allergy, enterosorbent, Enterosgel

INTRODUCTION

The incidence of food allergy varies, according to different literature sources, from 1% to 20%, and males are more predisposed to it [4, 5]. Food allergy is manifested by classical symptoms of allergy, including erythema and urticaria, as well as by gastrointestinal disturbances.

The most severe forms of food allergy are angioedema (Quincke's edema) and anaphylactic shock. Food allergy is most commonly manifested by reactions to one or two foods, while polyvalent food allergy (caused by multiple foods) is less frequent. It is presumed that a significant proportion of food reactions are pseudo-allergic or even toxic [9].

The diagnosis of food allergy is made in patients with any adverse reactions developing after a food is taken. According to the international classification adopted by the European Academy of Allergy and Clinical Immunology (EAACI), all kinds of adverse reactions to food can be subdivided into two groups as demonstrated in the Figure [10].

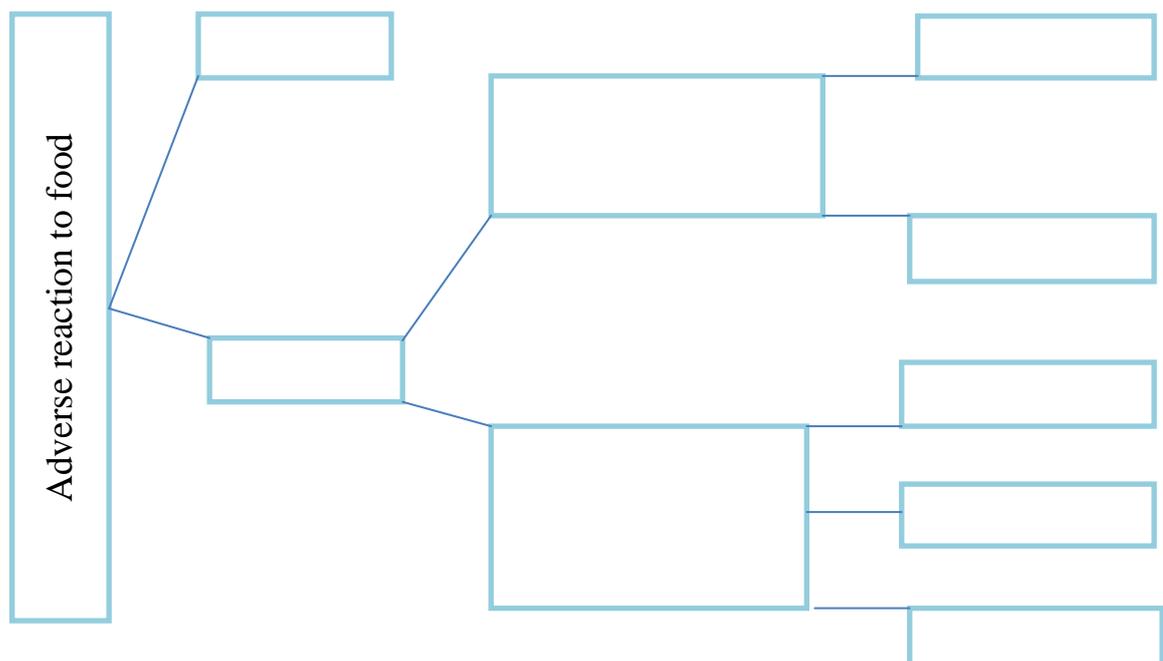


Figure. Adverse reactions to food EAACI classification (2001)

A true (immune-mediated) food allergy is either delayed-type or immediate-type hypersensitivity. Non-dietary histamine liberators (dyes, preservatives, flavours, thickeners, etc.), as well as microbial antigens, play an important role in food intolerances.

Adsorption therapy methods are employed for binding toxic products of foodstuffs, some components of food additives, and, particularly so, in patients with impaired protective mechanism of IgA-secretion required for oral food resistance. These methods include haemosorption, plasmapheresis, and enterosorption (binding and removal of toxic substances from the gastrointestinal tract) [4]. It should be mentioned that clinical practices most frequently utilize intestinal adsorption (enterosorption) as a simple and rather effective method of detoxification [3]. One of the most effective enterosorbents is Enterosgel, which exhibits selective sorptive activity towards middle-molecular-weight toxic metabolites [7, 8]. Some data are available that demonstrate the favourable effect of Enterosgel on immunological parameters in patients with various diseases [1, 2]. Our study was directed to evaluate the clinical efficacy of Enterosgel in patients with food allergy manifested by angioedema.

MATERIALS AND METHODS

The experimental group included 67 patients aged from 12 to 50 years who had food allergy and a history of various manifestations thereof ranging from mild erythema to angioedema. All study

subjects underwent immunological testing for presence of the inhibitor of the first component of the complement system (C_1 -inhibitor) to allow identification of the cause of the angioedema. Patients with any evidence of a possible familial history of the disease were excluded from the study.

The control group included 10 practically healthy volunteers aged from 17 to 45 years who were recruited to evaluate the effects of Enterosgel on immunological parameters.

The experimental group patients were administered conventional treatment in combination with the adsorbent Enterosgel: exclusion of allergenic foods from the diet, as well as desloratadine, calcium gluconate, and Enterosgel 15 g 2 times a day for 10 days.

Healthy subjects were given a course of Enterosgel, 15 g 2 times a day for 10 days.

All patients with food allergy underwent a clinical-immunological work-up for allergy: their allergic history was collected, a prick test for individual food allergens was staged, and serum concentrations of circulating immune complexes (CIC), immunoglobulins (Ig), interleukins (IL-5 and IL-6), and alpha- and gamma-interferons ($IFN-\alpha$ and $IFN-\gamma$) concentrations were determined. CIC were determined by sedimentation, using 3.75% polyethylene glycol solution (Serva, Germany), with subsequent spectrophotometry (Specord, Hungary), overall CIC levels were expressed in conventional optical density units.

Statistical analyses of study results were performed using the parametric Student's t-test.

RESULTS AND DISCUSSION

33 patients presented with skin manifestations of food allergy, which developed 10 to 50 minutes after a meal and ranged from perioral erythema to generalized urticaria and subsequent angioedema.

Apart from some of the aforementioned manifestations of food allergy, 24 patients also complained of facial angioedema, which had begun with swelling of the lips, soft tissues under the eyes, and the tip of the nose. Angioedema usually lasted 2 to 3 days and was eliminated within 10 to 20 hours in the patients administered antihistamine medication and the adsorbent Enterosgel.

10 patients had gastrointestinal complaints, including reactions to foods, which started with the events described above and were then accompanied by a single episode of vomiting, epigastric pain, or rapidly developing diarrhea. Skin manifestations of food allergy developed at a later time in these patients.

Subsequently, for the purpose of this study we selected the patients with angioedema, who had laboratory tests. Allergological tests (prick test) performed for 20 food allergens in these patients demonstrated that the most common reactions were those to citrus fruits ($n = 10$),

chocolate (n = 6), dairy products (n = 5), chicken egg allergens (n = 5), sea food (n = 3), and tomato-containing foods (n = 3). Simultaneous reactions to two allergens were detected in 12 study subjects, and reactions to three allergens in 5.

Outcomes of the treatment programme including the intestinal adsorbent Enterosgel in the patients with food allergy included improvement of skin reactions (in the prick test) to allergens: decreased dimensions of the hyperaemic area, pallor of spots that were first observed and then rapidly resolved.

The state of humoral immunity in the patients from the experimental group (with food allergy) and healthy subjects observed before and after treatment is presented in Table 1.

Table 1. Humoral immunity factors in patients with food allergy and in practically healthy subjects before and after Enterosgel treatment

Parameters	Groups			
	Healthy subjects (n = 10) (average value)		Patients with food allergy (n = 67) (average value)	
	Before treatment	After treatment	Before treatment	After treatment
IgE total (IU/ml)	67.0	64.0	166.6	92.5*
IgM (g/l)	2.1	2.0	1.9	2.2
IgG (g/l)	9.3	9.4	9.6	10.0
IgA (g/l)	2.3	2.0	2.4	2.2
IgG4 (g/l)	0.45	0.46	0.66	0.62
CIC (optical density units)	34.9	22.6	116.6	50.0*

Note: * p < 0.05.

The data shown imply that patients with food allergy had elevated total serum IgE concentrations (reference interval is 85–120 IU/ml) and CIC content. Enterosgel treatment was followed by normalization of these parameters in patients with food allergy (92.5 IU/ml), while no significant changes were observed in these parameters in the group of healthy subjects.

The cytokine profile studies revealed 3.8-fold and 2.5-fold elevations in IFN- γ and IL-5, respectively, in patients with food allergy, in contrast to controls (Table 2).

Table 2. Serum cytokine concentrations in patients with food allergy and in practically healthy subjects before and after Enterosgel treatment

Cytokine	Groups
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concentration (pg/ml)	Healthy subjects (n = 10) (average value)		Patients with food allergy (n = 67) (average value)	
	Before treatment	After treatment	Before treatment	After treatment
IFN- α	2.8	2.6	3.5	6.2*
IFN- γ	68.0	74.5	258.8*	206.6*
IL-5	2.5	2.7	6.6*	1.4*
IL-6	42.6	41.7	107.2*	72.5

Note: * p < 0.05.

As a result of treatment, patients with food allergy had a statistically significant reduction in the content of the pro-allergic cytokine IL-5; however, the IFN- γ level did not change significantly, although a trend towards lower concentrations was observed in 55% of patients. A significant increment in early IFN- α concentrations was demonstrated in patients with food allergy who took the adsorbent Enterosgel.

CONCLUSIONS

1. The increased total serum IgE concentrations in study subjects demonstrated a reagin-dependent type of food allergy and allowed to classify this condition as a true allergy [6].
2. Apart from the increased IgE concentrations, patients with food allergy had increased circulating immune complexes, IFN- γ , IL-5, and IL-6 concentrations. No such deviations were observed in healthy controls.
3. Inclusion of the intestinal adsorbent (enterosorbent) Enterosgel in the treatment programme for patients with food allergy significantly improves their allergy status and promotes normalization of the total serum IgE levels, early IFN- α and the pro-allergic cytokine IL-5.
4. The reported study demonstrates the value of intestinal adsorption, in particular with Enterosgel, as part of treatment for patients with food allergy manifested by angioedema.

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