

UDC 616.433.664\_053.31\_08

**O.K. Koloskova**  
**U.I. Marusyk**  
**O.V. Belashova**

*Bukovyna State Medical University  
(Chernivtsi)*

## THE USE OF HYPOALLERGENIC MIXTURES IN CHILDREN WITH SIGNS OF ATOPY

**Key words:** children, food allergy, atopy, dermatitis, partial protein hydrolyzate.

**Abstract. Introduction.** Studies are indicative that about a quarter of infants in Ukraine have atopic manifestations. If the breastfeeding is impossible, hypoallergenic mixtures should be used. **The aim of the research.** To establish clinico-paraclinical efficacy of hypoallergenic mixtures TM "Humana Ha" in infants with clinical manifestations of atopic abnormality of constitution. **Methods.** 27 children aged from 2 to 12 months with the symptoms of atopic dermatitis and 25 infants who were fed on formula and had the usual signs of wheezing syndrome underwent complex examination. **Results.** In the 1st clinical group among patients with mild forms of eczema (11,1%) score on EASI scale decreased from  $28,8 \pm 2,1$  to score  $12,2 \pm 1,8$  score ( $P < 0,05$ ). The using mixture "Humana-HA" was led to a decrease in absolute risk register high concentration of IL-4 in serum by 20,9%, relative risk reduction – 23,5% (95% CI 15,5-33,1), and the minimum number of patients which should be treatment to get one positive result was 4,2 (95% CI 1,2-10,4). **Conclusions.** The using of partially hydrolyzed mixture "Humana-HA" in infants with signs of atopic dermatitis significantly improves the flow of mild and moderate forms. Application of partial protein hydrolyzate "Humana-HA" in the diet of infants with atopic dermatitis reduces the content of immunoglobulin E and interleukin-4 in serum.

### Introduction

Continuous growth of allergic disease in young children today resulted in the actuality and importance of this disease's prevention [1,3]. The studies which were conducted over the last 10 years showed that about a quarter of infants in Ukraine have atopic manifestations [2]. However, almost in one-third of the population allergic diseases are formed only due to the influence of environmental incentives [4,5] which for infants primarily serve food allergens, including cow's milk proteins (CMP). Allergy to CMP is detected in 0,3% of infants and 7,5% of young children [6]. Primary prevention of food allergy to cow's milk protein allergy is the prevention of the formation of a child's phenotype in the future.

Modern approaches to non-drug measures for primary prevention of allergies in children predict preservation of breastfeeding for all children without exception [7]. When the breastfeeding is impossible it should be used hypoallergenic alternatives [8,9,10].

According to the requirements of the European Union pediatricians, gastroenterologists, nutritionists hypoallergenic mixture should be characterized by good tolerability in 90% of children suffering from allergies to CMP, contain low residual amount of antigens, to meet rates of growth and development of children. Hypoallergenic mixture TM "Humana HA" satisfies these requirements. These products have

therapeutic and prophylactic properties and can be used to prevent and treat food allergies of mild and moderate severity.

### The aim of the research

To establish clinico-paraclinical efficacy of hypoallergenic mixtures TM "Humana Ha" in infants with clinical manifestations of atopic abnormality constitution.

### Material and Methods

To achieve this aim a dynamic integrated clinico-immunological surveillance examination of 27 children aged from 2 to 12 months with the symptoms of atopic dermatitis (I clinical group) has been carried out. 25 infants who were fed on formula and had the usual signs of wheezing syndrome constited a referent group. All children were examined in the department for children under 1 year of Regional Children's Clinical Hospital, Chernivtsi, and the average length of the dynamic supervision was  $3,2 \pm 0,06$  months. As to the main clinical parameters groups were collated.

Severity of atopic dermatitis symptoms was assessed on an EASI scale [11] according to the clinical trials program of the hypoallergenic baby food mixtures TM "Humana HA". Criteria for evaluating of the effectiveness of nutrition were:

indicators of therapeutic efficacy (recurrent symptoms of atopic dermatitis (AD)) and changes of immunological research indicators. The manifestations of AD in children were determined in a rash of different localization and character, dryness, redness, swelling, itching of the skin. In addition, cracks, scales, crusts on the skin were registered.

Along with clinical observations it was conducted a complex immunological blood test II - III levels, including content of interleukin-4 (IL-4) and immunoglobulin E (Ig E) in serum.

The work was done due to randomized comparative study in parallel groups by an "experiment-control" method. The results were analyzed by methods of variational statistics using statistical software StatSoft Statistica v5.0. and clinical epidemiology. The effectiveness of the treatment was evaluated taking into account a decrease of the absolute risk (DAR), relative (DRR) risk, as well as the minimum number of patients (MNP), which should be treated to get one positive result. The critical significance level "p" when checking statistical hypotheses in this study received equal 0,05.

#### Discussion of the study results

Against a background of using hypoallergenic mixture TM "Humana HA" its good tolerability, a significant improvement of appetite and sleep was observed in all children. In 11 children (40,7%) with the symptoms of AD during using the hypoallergenic mix "Humana HA-2" a significant positive clinical dynamics was observed: all symptoms since the 3rd day, gradually decreased and completely disappeared before the 14th day of observation. In 5 children (18,5%) with AD during using the mixture maximal effect was observed in 3 - 5 days. Rash, redness, itching were gone, but dry skin, single rashes various locations were kept to the end of the study. New skin manifestations in these children were not observed.

According to the utilized scale for evaluation of the area and atopic dermatitis severity (EASI), significant improvements against a background of feeding of hypoallergenic infants have occurred. Thus, in the I clinical group among patients with mild forms of eczema (11,1%) score on this scale decreased from  $28,8 \pm 2,1$  to  $12,2 \pm 1,8$  ( $P < 0,05$ ). In the subgroups of children with moderate (66,6%) and severe course of the (22,2%) disease the same changes were:  $50,1 \pm 1,9$  and  $27,6 \pm 1,7$  in the first case and  $65,6 \pm 1,5$  versus  $39,3 \pm 1,4$  ball - in the second ( $P < 0,05$ ). Transformation to lighter variants of atopic dermatitis clinical course in 66,6% of children with mild and moderate symptoms and only 33,3% - with severe, which is underlining higher efficacy of hypoallergenic products under study in

the diet of mild and moderate forms of atopic diseases has been marked.

According to the literature [12,13], allergic inflammation is accompanied by some changes in the immune status of patients, such as increased number of T - lymphocytes the function of which is associated with a helper, a decrease of T - cell subpopulations, whose function is associated with suppressor. Enhanced response of T-helper cells is accompanied by increased production of interleukin-4, under which there is hypersecretion of total immunoglobulin E - an objective marker of atopy. Due to increased concentrations of serum total immunoglobulin E and the role of interleukin-4 in atopic diseases it was expedient to determine the parameters of the humoral immune system in children of the group under observation (Table).

Table

The content of IL-4 and total immunoglobulin "E" in the serum of children

Clinical group	Number of children	IL-4, pg/ml	IgE, kU/l
I	27	$30,1 \pm 2,9$	$824,0 \pm 87,4$
II	25	$24,4 \pm 2,7$	$144,6 \pm 42,3$
P: I:II		$>0,05$	$<0,01$

As can be seen from the data, significant differences as to the content of IL-4 in the serum were not found between groups of patients, although the content of IgE differences was statistically significant. At the same time, among patients who did not receive hypoallergenic mix "Humana HA" significantly greater part of children was marked in the serum which the content of IL-4 was determined more than 40 pg / ml, regarding to children who were bottle-fed with hypoallergenic blend ( $33,3 \pm 6,8\%$  versus  $11,5 \pm 5,1\%$ ,  $p < 0,05$ ). It should be noted that the using mixture "Humana-HA" was led to a decrease in absolute risk register high concentration of IL-4 in serum by 20,9%, relative risk reduction - 23,5% (95% CI 15,5-33,1), and the minimum number of patients which should be treatment to get one positive result was 4,2 (95% CI 1,2-10,4).

Thus, the results of clinico-immunological studies show that children had bear well "Humana-HA" mix pure, it can be recommended for use in the diet of infants with food allergy symptoms or the risk of its development and atopic dermatitis.

#### Conclusions

1. Using the hypoallergenic mix "Humana-HA" led to disappearance of atopic dermatitis signs in almost every second child from 2 to 12 months.

2. Using partially hydrolyzed mixture "Humana-HA" in infants with signs of atopic dermatitis

significantly improves the flow of mild and moderate forms.

3. Application of partial protein hydrolyzate "Humana-NA" in the diet of infants with atopic dermatitis reduces the content of immunoglobulin E and interleukin-4 in serum, a minimum number of patients which should be treatment to get one positive result is 4.2 (95% CI 1,2-10, 4).

### Prospects for further research

To estimate the effect of hypoallergenic blends as to the parameters of cell's link of children with atopy signs.

**References.** 1. Besch L.V. *Perinatologia ta pediatria - Perynatology and pediatrics*, 2010, no.2 (42), pp. 27-31. (in Ukr.) 2. Ohotnikova O.M. *Dutiachui likar – Pediatrician*, 2011, no.2, pp. 26-35. (in Ukr.) 3. Arshad S.H. *J. Allergy Clin Immunol*, 2005, vol. 116, no.1, pp. 3-14. 4. Akdis C.A., Akdis M. *Clin Exp Allergy*, 2003, no.33, pp. 1618-1621. 5. Scadding G.K. *Clin Exp Allergy*, 2007, vol.37, no.4, pp.485-487. 6. Lack G. *J. Allergy Clin Immunol*, 2008, vol.121, no.6, pp. 1331-1336. 7. Host A., Halken S., Muraro A. *Pediatr. Allergy Immunol*, 2008, vol.19, pp. 1-4. 8. Gore C., Custovic A. *Paediatric Respiratory Reviews*, 2003, vol.4, pp. 213-224. 9. Prescott S.L., Smith P., Tang M. *Pediatr. Allergy Immunology*, 2008, vol.19, pp. 375-380. 10. Rona R.J., Kell T., Summers C. *J. Allergy Clin Immunol*, 2007, vol.120, no.3, pp. 638-646. 11. Hanfin J.M., Thurston M., Omoto M. *Exp. Dermatol*, 2001, vol.10, pp. 11-18. 12. Nieto A, Mazon A, Martin-Mateos A. *Pediatr Allergy Immunol*, 2011, vol.22, no.7, pp. 742-750. 13. Vandenbulecke L., Bachert C., Cauwenberge P. V., Claeyss S. *Int Arch Allergy Immunol*, 2006, vol.139, pp. 159-165.

### ВИКОРИСТАННЯ ГІПОАЛЕРГЕННОЇ СУМІШІ У ДІТЕЙ З ОЗНАКАМИ АТОПІЇ.

*О.К. Колоскова, У.І. Марусик, О.В. Бєлашова*

**Резюме.** Вивчено ефективність гіпоалергенних молочних сумішей у дітей грудного віку з клінічними проявами atopічної аномалії конституції з урахуванням показників толерантності до нової їжі, динаміки проявів atopічного дерматиту, концентрації інтерлейкіну-4 та імуноглобуліну Е в сироватці крові. Виявлено, що вживання гіпоалергенної суміші «Humana –NA» призводить до зникнення ознак atopічного дерматиту практично у кожній другій дитині віком від 2 до 12 місяців, значно покращує перебіг легких і середньо тяжких його форм, сприяє нормалізації процесів травлення і вагової прибавки, знижує вміст імуноглобуліну Е та інтерлейкіну 4 в сироватці крові.

**Ключові слова:** діти, харчова алергія, atopія, дерматит, часткові білкові гідролізати.

### ПРИМЕНЕНИЯ ГИПОАЛЛЕРГЕННЫХ СМЕСЕЙ У ДЕТЕЙ С ПРИЗНАКАМИ АТОПИИ.

*О.К. Колоскова, У.И. Марусык, О.В. Бєлашова*

**Резюме.** Изучена эффективность гипоаллергенных молочных смесей у детей грудного возраста с клиническими проявлениями atopической аномалии конституции с учетом показателей толерантности к новой пище, динамики проявлений atopического дерматита, концентрации интерлейкина-4 и иммуноглобулина Е в сыворотке крови. Выведено, что употребление гипоаллергенной смеси «Humana-NA» приводит к исчезновению признаков atopического дерматита практически у каждого второго ребенка в возрасте от 2 до 12 месяцев, значительно улучшает течение легких и среднетяжелых его форм, способствует нормализации процессов пищеварения и весовой прибавки, снижает содержание иммуноглобулина Е и интерлейкина - 4 в сыворотке крови.

**Ключевые слова:** дети, пищевая аллергия, atopия, дерматит, частичные белковые гидролизаты.

*Clin. and experim. pathol. - 2013. - Vol.12, №3 (45). - P.82-84.*

*Надійшла до редакції 03.09.2013*

*Рецензент – проф. Т.В.Сорокман*

*© О.К. Koloskova, U.I. Marusyk, O.V. Belashova, 2013*