

The Effects of Dietary Counseling on Children with Food Allergy: A Prospective, Multicenter Intervention Study

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ABSTRACT

Although dietary counseling is generally recommended in children with food allergy (FA), its effect on the nutritional status of these patients has not yet been evaluated. Our nonrandomized multicenter prospective intervention study was undertaken to investigate the effects of dietary counseling on children with FA. Anthropometric data, dietary intakes, and laboratory biomarkers of nutritional status were evaluated in children with FA (aged 6 to 36 months) before and after dietary counseling, by multidisciplinary teams composed of pediatricians, dietitians, and nurses. Ninety-one children with FA (49 boys and 42 girls; mean age 18.9 months, 95% CI 16.5 to 21.3) were evaluated; 66 children without FA (41 boys and 25 girls; mean age 20.3 months, 95% CI 17.7 to 22.8) served as controls providing baseline values only. At enrollment, energy and protein intakes were lower in children with FA (91 kcal/kg/day, interquartile range [IQR]=15.1, minimum=55.2, maximum=130.6; and 2.2 g/kg/day, IQR=0.5, minimum=1.5, maximum=2.7, respectively) than in children without FA (96 kcal/kg/day, IQR=6.1, minimum=83.6, maximum=118.0; and 4.6 g/kg/day, IQR=1.2, minimum=2.0, maximum=6.1, respectively; $P<0.001$). A weight to length ratio <2 standard deviations was more frequent in children with FA than in children without FA (21% vs 3%; $P<0.001$). At 6 months following dietary counseling, the total energy intake of children with FA was similar to the baseline values of control children. Dietary counseling also resulted in a significant improvement of their anthropometric and laboratory biomarkers of nutritional status. The results of our study support the crucial role of dietary counseling in the clinical management of children with FA.

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FOOD ALLERGY (FA) IS A MAJOR HEALTH ISSUE FOR children living in Western countries.¹ Management of FA consists of strict elimination of the offending allergen from the diet until tolerance is acquired.¹ FA predominates in early childhood during the vulnerable period of rapid growth, when inadequate nutrition could have an influence on adult health. Eight foods (cow's milk, hen's egg, soy, peanuts, tree nuts, wheat, fish, and shellfish) account for more than 90% of childhood cases of FA.¹ Most of these foods have a high nutritional value and are affordable for children living in Western countries. Inappropriate elimination diets in children with FA can induce vitamin and mineral deficiencies, anemia, rickets, failure to thrive, and kwashiorkor.²⁻⁴ Dietary counseling is recommended to prevent these conditions,^{1,5,6} but the effect of this service on the nutritional status of patients with FA has never been explored. The aim of our study was to investigate the effects of dietary counseling on growth, energy intakes, and on laboratory biomarkers of nutritional status in children with FA.

METHODS

Study Design

Our nonrandomized, prospective, multicenter intervention study was conducted between September 2006 and March 2008 in outpatient children with FA (aged 6 to 36 months) who were following an elimination diet without dietary counseling for at least 60 days. These children were consecutively referred for consultation to two tertiary centers for pediatric allergy and nutrition (located in Milan and Naples, Italy, respectively). Exclusion criteria were a history of prematurity (<37 gestational weeks), systemic diseases, cardiovascular diseases, hematologic diseases, chronic respiratory diseases, psychiatric disorders, renal failure, neurologic impairment, active tuberculosis, autoimmune diseases, immunodeficiency, chronic inflammatory bowel diseases, gastroesophageal reflux disease, celiac disease, cystic fibrosis, metabolic or endocrine diseases, genetic defects, malignancies, and malformations of the gastrointestinal or the urinary tract.

At each center, the children with FA were seen by a pediatrician and a dietitian who evaluated the medical history and clinical condition and verified the diagnosis of FA according to standard criteria.^{1,7} If the diagnosis of FA was confirmed, the pediatrician invited the parents to participate in the study. When parents provided written informed consent to participate in the study, they were asked to complete, prospectively, a 3-day food record in the form of a printed chart and to return the chart to the center within 1 week, when the enrollment visit (T0) was planned. The dietitian explained to parents how to record the amount and type of foods and drinks consumed by the child over a period of 3 consecutive days, including 2 weekdays and 1 weekend day. The chart also contained instructions about how to record the food consumed and how to measure food using graduated bowls, cups, dishes, and spoons. At the enrollment visit (T0) and 2 (T1), 4 (T2), and 6 months (T3) thereafter, the children with FA were evaluated by a multidisciplinary team composed of a pediatrician, a nurse, and a dietitian.

During the same period (namely, between September 2006 and March 2008) healthy children without FA (aged 6 to 36 months) consecutively evaluated at the centers before undergoing minor surgical procedures (eg, penile manipulation, inguinal hernia repair, and cyst excisions) were enrolled as nonmatched controls. The same exclusion criteria applied to the control group of children. Their parents, after providing informed consent, received instructions on how to complete the 3-day food record for the child. The control children were examined only at T0 by a multidisciplinary team.

At T0, the children of the two groups were evaluated when they were free of infectious diseases, medication use, trauma, vomiting, and diarrhea during the previous 3 weeks. Weight, length or height, and head circumference were measured using standard procedures.⁸ Anthropometric indexes (*z* score for weight, *z* score for length/height, and *z* score for head circumference) were determined using the Euro-Growth References.^{9,10} The medical record of each child was recorded on a clinical chart. The study was approved by the Ethics Committee of each Institution and was registered in Clinical Trials Protocol Registration System (ID no: NCT01583907).

Dietary Assessment and Counseling

At T0, the dietitian examined the dietary history and reviewed the 3-day food records of the two groups of children. The assessment of dietary history included the child's food preferences, food aversions, and behavior problems at mealtimes. Diaries were analyzed using specific software based on the Italian food composition tables (Winfood Pro 2.5, 2006, Medimatica Srl). At this enrollment visit, the children with FA underwent a personalized dietary counseling session. Dietary counseling was based on the evaluation of body weight, length/height, weight to height ratio, and head circumference; rate of required catch-up growth (based on weight to height ratio or standard deviation [SD] scores) and its feasibility depending on the patient's current dietary intake and allergen restriction; and protein and energy requirements.

The dietitian suggested dietary changes based on the 3-day food record. The dietitian counseled parents about issues that could arise during an elimination diet and how to replace the allergenic foods with an alternative source of nutrients to reach the daily recommended intake for Italian children adjusted for age and sex.¹¹ In patients with cow's milk allergy

(CMA), the daily amount of substituted formula was determined, and an increase of formula concentration was proposed when necessary. In children affected by other forms of FA or by multiple FA, a list of antigenic foods was given to the parents, and inappropriate elimination of other foods was discouraged. When necessary, the total energy intake was customized according to calculated needs for catch-up growth. A fixed diet was never ordered, the families were encouraged to gradually introduce small changes to improve the child's diet. The key words and phrases used during dietary counseling were emphasized to encourage discussion about the food-related topics at home. Six months later (ie, at T3) the parents of the children with FA were asked to complete another 3-day food record that was also reviewed and edited by the dietitian.

Laboratory Measurements

At T0 a venous blood sample was collected from children with FA and from healthy controls (before the minor surgical procedures) to determine serum biomarkers of nutritional status, namely, hemoglobin, iron, albumin, total cholesterol, triglycerides, calcium, phosphorus, and zinc.⁸ Plasma fatty acid levels were also determined by capillary gas chromatography after lipid extraction according to Folch and colleagues.¹² A second blood sample was collected 6 months later (ie, at T3) only from children with FA. Blood was sampled after an overnight fast.

Statistics

Eighty-five patients were required to obtain a power of the study of 90%, a type 1 error of 0.05 by two-tailed test. This estimate assumes a mean increase of the *z* score for weight after nutritional intervention of 0.5 (from -0.5 at T0 to 0.0 at T3, with an SD of 1), whereas 60 per group were required (power of the study of 90%, type 1 error of 0.05 by two-tailed test) assuming a difference of 1 between children without FA (0.5 ± 1.5) and patients with FA (-0.5 ± 1.5) in the *z* score for weight at T0. These computations were based on the expectations arising from the results of a preliminary open trial. For continuous variables, groups were compared using the test of equality of means. The χ^2 test and Fisher's exact test were used for categorical variables. A multivariate analysis using the general linear model for repeated measures was used to evaluate the influence on the primary study outcome of the following variables: age, sex, allergen, single or multiple FA, duration of exclusion diet before enrollment, age at diagnosis of FA, symptoms, and type of formula. When necessary, comparisons were performed with nonparametric tests (ie, Mann Whitney *U* test). Results were reported as means and 95% CI and as median and interquartile range (IQR) plus minimum and maximum range due to nonnormal distribution (established by the Kolmogorov test). The level of significance for all statistical tests was two-sided ($P < 0.05$). All data were collected in a dedicated database and analyzed by a statistician blinded to patients' group assignment with SPSS version 13.0 for Windows (2004, SPSS Inc).

RESULTS AND DISCUSSION

From September 2006 to March 2008, 107 children with suspected FA were considered for the study. Nine patients were excluded because of concomitant other diagnoses (4

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