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Original Article

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Clinical-Epidemiological Characterization of Patients with Cow Leit Protein Allergy

Delmis Esther Montero Verdecia I https://orcid.org/0000-0002-5800-5109

Mirtha Ofelia Rondón Peña I https://orcid.org/0000-0003-0357-7211

Suzanne Santiesteban Puerta II https://orcid.org/0000-0003-2357-9337

Katherine de la Caridad Garrido Benítez II https://orcid.org/0009-0004-7495-5392

Yunior Meriño Pompa II* https://orcid.org/0000-0002-2631-8274

[Yo]Granma University of Medical Sciences. Hermanos Cordové Children's Hospital. Manzanillo, Granma, Cuba.

[II]Celia Sánchez Manduley School of Medical Sciences. Manzanillo, Granma, Cuba.

* Corresponding author. Email:yuniormp9911@nauta.cu

SUMMARY

Cow's milk protein allergy appears in the first months of life and is the most common food allergy in infants and young children. This study aims to clinically and epidemiologically

characterize patients with cow's milk protein allergy. A longitudinal, descriptive, retrospective study was conducted at the Hermanos Cordové Children's Hospital in the Manzanillo municipality of Granma, Cuba. The population consisted of 10 infants discharged from the institution during the period 2017-2021. The variables studied were age, sex, length of stay, duration of disease, breastfeeding, risk factors, and nutritional assessment. Key findings included a predominance of females and ages from one to six months (60%). Fifty percent of children were malnourished. Diarrhea was the main symptom of 70% of patients, followed by skin lesions (60%). Only 20% were exclusively breastfed until 6 months of age. Cesarean delivery was the most prevalent risk factor (50%). It was concluded that female sex and ages between one and six months were the most prominent. Diarrhea and skin lesions were the most frequent clinical manifestations in patients with cow's milk protein allergy. Malnourished infants, those on formula, and those with a history of cesarean delivery were more likely to develop this disease.

Keywords: Cow's milk; Allergic reaction; Immunoglobulin E; Allergens.

ABSTRACT

Allergy to cow's milk proteins, appears in the first months of life and is the most common food allergy in infants and young children. This research aims to characterize clinically and epidemiologically patients with allergy to cow's milk proteins. A longitudinal, descriptive, retrospective study was conducted at the Hermanos Cordové Children's Hospital in the municipality of Manzanillo in Granma, Cuba. The population consisted of the 10 children who graduated from the institution during the period 2017-2021. The following variables were studied: age, sex, length of stay, duration of disease progression, breastfeeding, risk factors, nutritional assessment. Among the main results, it was found that the female sex and the ages of one to six months predominated (60%). The 50% of children were malnourished. 70 % of patients had diarrhea as the main symptom, followed by skin

lesions (60 %). Only 20 % were exclusively breastfed up to 6 months of age. Caesarean section was the most prevalent risk factor (50%). It is concluded that the female sex and the ages of one to six months were the most outstanding. Diarrhea and skin lesions were the most common clinical manifestations in patients with cow's milk protein allergy. Malnourished infants, breastfed infants and a history of cesarean delivery are more likely to have this disease.

Keywords: Cow's milk; Allergic reaction; Immunoglobulin E; Allergens.

SUMMARY

An allergy to cow's milk protein appears in the first months of life and is a food allergy that is more common in infants and small children. This research aimed to clinically and epidemiologically characterize patients with cow milk protein allergy. A longitudinal, descriptive and retrospective study was carried out at the Hermanos Cordové Children's Hospital, in the municipality of Manzanillo, in Granma, Cuba. The population was composed of 10 children who were trained in the institution in the period from 2017 to 2021. The following variables were studied: age, sex, time of hospitalization, time of child development, maternal age, risk factors, nutritional assessment. Among the main results, the female sex predominated and the age ranged from one to six months (60%). 50% of children are malnourished. Diarrhea was the main symptom in 70% of two patients, followed by skin lesions (60%). Only 20% are exclusively breastfed within 6 months of life. Or cesarean section birth was the most prevalent risk factor (50%). It was concluded that the female sex ranged from one to six months to the ones that stood out the most. Diarrhea and skin lesions are the most frequent clinical manifestations of patients with cow's milk protein allergy. Malnourished infants, formula-fed infants, and a history of cesarean delivery are more likely to suffer from malnutrition.

Keywords:cow's milk; Allergic reaction; Immunoglobulin E; Allergens.

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Introduction

Cow's milk (CM) is one of the most consumed foods in the world. Some consider it essential for children and others call it poison. Its bad reputation stems from the high frequency with which it produces allergies or intolerances. (1) Among its benefits are the contribution of essential nutrients, calcium, potassium and vitamin D, among others; it also reduces the risk of diseases such as hypertension and metabolic syndrome. (2)

Its consumption can also cause discomfort, mainly due to enzyme deficiency, lactose intolerance or allergic reaction, which is described as cow's milk protein allergy (CMPA), the most common in children and involved in a variety of hypersensitivity reactions. (3,4)

It becomes an unexpected "second wave" of the epidemic within the category of non-infectious diseases, especially in the last 15-20 years, its frequency in infants and preschool children has increased dramatically, reaching, in some countries, a prevalence of around 10%, with an increase also in severe reactions. (5)

Labeled as a serious health problem that jeopardizes the proper development of oral tolerance in infants, as well as their proper growth and development. Every child is at risk of developing the allergy, but genetic inheritance, early exposure to the allergen, environment, variety of births, and diet are some of the risk factors that intervene and increase or decrease the likelihood of its appearance in children. (5-7)

CMPA includes IgE-mediated (immediate type I), non-IgE-mediated (cellular), and mixed (immediate and delayed) adverse reactions. The gastrointestinal tract plays a key role in

this, as an immunological organ that acts through lymphoid tissue and possesses a broad network of cells that interact with the environment to protect against the entry of external substances. (7)

The prevalence of bovine milk protein allergy worldwide is 1.12%. (8) Another cohort study in the region, but in children under 24 months of age, found an incidence of 0.7%. In Iceland, Germany, Spain and Lithuania, every child with a positive oral challenge to VL also has a positive test for specific IgE; however, in the United Kingdom, the Netherlands, Poland and Italy there are cases of allergy with a negative IgE test. (9)

Other international medical literature recognizes that prevalence varies according to racial group and dairy product consumption habits; in the United States of America, 6% of children suffer from it and 3% of indigenous children in Norway, but in countries such as Korea, it does not exceed 0.3%. (10,11)

However, specific reports on CMPA in Latin America are scarce; according to reported figures, the prevalence of cow's milk protein allergy in children under 1 year of age can be as high as 7.5%. (4) In Chile, Camila Cordero et al. showed in their study a prevalence ranging from 2 to 7%. (12)

In addition, it is mentioned that today, in the thinking of the general comprehensive physician or the Cuban pediatrician, the disease is not integrated as a serious health problem on the rise, due to the low rate of exclusive breastfeeding (EBF) in newborns and infants. (13)

According to data provided, the country shows a 66.7% rate of introduction of artificial lactation in both age groups, which translates into an increased potential risk of suffering from it. Therefore, it is frequently not suspected, and therefore, diagnosis and treatment are delayed. (14)

The institutional incidence of the condition is also unknown, as there are no records from previous years to support this, a fact that undoubtedly hinders the development of

research.

New cases are still being reported, which warns that it is necessary to think about the disease itself. This circumstance represents a cognitive gap and stands as an obstacle to developing and perfecting the medical care process in the hospital, a space that is useful and necessary to fill with recent studies. This is the motivation that the group of authors had to carry out this work, which is based on and guided by the proposition of the following research question: what clinical and epidemiological features characterize patients diagnosed with cow's milk protein allergy, treated at the "Hermanos Cordové" Children's Hospital during the period 2017 - 2021?

What is expressed in the problem statement is an unfavorable situation, which is why conducting this research is an absolute and urgent necessity.

Important data on the disease were identified, filling the aforementioned information gap. These data will serve as the basis for the future development of an institutional Guide to Good Clinical Practices, with the potential for generalization. This guide is based on the best scientific evidence and appropriate to national circumstances. This guide will facilitate diagnosis, timely treatment, and follow-up of the disease, prevent complications, and improve the quality of life of patients suffering from it. If all of this is achieved, the current study will be given social and practical value.

The objective is to clinically and epidemiologically characterize patients with cow's milk protein allergy.

Methods

Type of study:A longitudinal, descriptive and retrospective study was carried out on patients suffering from cow's milk protein allergy, admitted to the "Hermanos Cordové" Children's Hospital, in the Manzanillo municipality, Granma province, during the period

2017 - 2021.

Universe: The population consisted of 10 patients discharged from the institution during the reference period with a diagnosis of cow's milk protein allergy. No sampling criteria were used for the study.

Inclusion criteria: Patients under two years of age whose clinical records reflected cow's milk protein allergy as a diagnosis.

Exclusion criteria: Patients whose clinical records presented errors or omissions that invalidated the information necessary for the study or made it unreliable.

Study variables:

1. Age: [assessed according to themonths completed (newborn; 1-6 months; 7-12 months; 13-24 months)].
2. Sex: [defined according to the biological sex of belonging (female or male)].
3. Stay: [evaluated according to the number of days spent in the hospital (up to 5 days or less than 5 days)].
4. Nutritional assessment: [evaluated according to Cuban pediatric standards. Weight/height percentiles (malnourished: -3P; thin: 3-10P; normal weight: 10-90P)].
5. Time of evolution of the disease: [discrete quantitative: Time between the appearance of symptoms and signs and the diagnosis of the disease (0-24 hours and 25-48 hours)].
6. Symptoms and signs: [these are the clinical manifestations of the disease: (diarrhea, skin lesions, vomiting, pale skin and mucosa, rhinorrhea, cough).
7. Breastfeeding: [evaluated according to the milk administered](maternal; artificial; mixed)].

8. Risk factors: [factors that increase the chances of suffering from the disease (personal atopy; family atopy; cesarean delivery)].
9. Complementary tests: [analysis indicated for the patient for diagnosis: (complete blood count; absolute eosinophil count; serum IgE determination; Ig quantification)].

Theoretical level methods:

Synthetic Analytical: during the rational analysis of the existing theoretical knowledge in the bibliographic sources on the disease, and in the understanding and summarized expression of the phenomenon and its properties.

Logical history: to search for and obtain information present in bibliographic sources related to the condition, and to establish its behavior in chronological succession, in order to then coherently express the essence of that movement.

Induction and deduction: for the process of abstraction and ascension of knowledge and to explain the essence and relationships of the object of study.

Empirical level methods:

Unstructured observation: to verify the declared problem in the physical, psychological and social aspects.

Measurement: in the tangible expression of the quantitative and qualitative aspects of the characteristics inherent to the object of study, through absolute numbers, percentages, rates, arithmetic means, etc.

Document review: Medical records, the hospital's Medical Records and Statistics Department's data control book, the Allergy clinic's record book, and the Gastroenteritis ward discharge book were reviewed to obtain information about the patients being studied.

Clinical-epidemiological: for the exploration and recognition in the subjects studied, of the characteristics related to the determining aspects in the health-disease process corresponding to CMPA which, by linking them to the general population, will allow establishing the links between the biological and the social.

Statistical methods:

Descriptive statistics: to determine, process, and describe the quantitative results obtained through the processing of information related to the patients under study. The statistical software SPSS (Statistical Package for the Social Sciences) version 11.5 in Spanish for Windows was used, and percentage calculation was used as a summary measure.

Descriptive statistical measures (mean and standard deviation) were used to summarize continuous quantitative variables through the data analysis option within MS Excel Tools.

The morbidity rate of patients diagnosed with CMPA was estimated from the point rate and the overall rate using the following formulas:

Annual rates: calculated based on the number of admissions for cow's milk protein allergy per year, divided by the total number of admissions to the gastroenteritis ward per year. The result is then multiplied by 100.

Overall rate: This is calculated based on the number of admissions for cow's milk protein allergy during the period, divided by the total number of admissions to the gastroenteritis ward during the period. The result of this calculation is then multiplied by 100.

Results

Table 1 shows the predominance of the female sex (60%) and the majority of newborns were between 1 and 6 months old, which represents 60%.

Table 1. Patients with CMPA by age and sex.

Age groups (months)	Sex				Total	
	Female		Male			
	No	%	No	%	No	%
Newborn	1	10.0	-	-	1	10.0
From 1-6	4	40.0	2	20.0	6	60.0
From 7-12	-	-	1	10.0	1	10.0
From 13-24	1	10.0	1	10.0	2	20.0
Total	6	60.0	4	40	10	100

Fountain: Medical records.

In the present study, the most common length of stay was less than 5 days, accounting for 70% of the cases. Regarding nutritional status, 50% were malnourished, which has been explained by this group's vulnerability to immunological disorders. (Table 2)

Table 2. Stay with patients with CMPA and their nutritional assessment.

Variable	Patients	
	No.	%*
Stay		
Up to 5 days	7	70
More than 5 days	3	30
Nutritional assessment		
Malnourished	5	50
Slim	3	30
Normal weight	2	20

Fountain: Medical records.
*Total patients with CMPA=10.

Diarrhea was the main symptom in 70% of patients, followed by skin lesions, which accounted for 60% of cases, with a predominance of 0 to 24 hours in terms of time of

onset. (Table 3)

Table 3. Patients according to the time of evolution of CMPA.

Symptoms and signs	Evolution time				Total	
	From 0-24 hours		From 25-48 hours			
	No	%*	No	%*	No	%*
Diarrhea	5	50	2	20	7	70
Skin lesions	4	40	2	20	6	60
Vomiting	3	30	1	10	4	40
Cutaneous and mucosal pallor	3	30	1	10	4	40
Rhinorrhea	2	20	1	10	3	30
Cough	5	50	2	20	7	70

Fountain: Medical records.
*Total patients with CMPA=10.

Only 20% received EBF until 6 months of age, which increases the risk of CMPA, coupled with the introduction of new foods into the diet. (Table 4)

Table 4 Patients by age group and breastfeeding.

Age groups	Type of breastfeeding						Total	
	Maternal		Artificial		Mixed			
	No	%*	No	%*	No	%*	No	%*
Newborn	1	10	-	-	-	-	1	10
From 1-6 months	1	10	3	30	2	20.0	6	60
From 7-12 months	-	-	1	10	-	-	1	10
From 13-24 months	-	-	2	20	-	-	2	20
Total	2	20	6	60	2	20.0	10	100

Fountain: Medical records.

Among the risk factors for CMPA, cesarean delivery predominated in 50% of cases, and in terms of complementary tests, a complete blood count was performed on all patients. (Table 5)

Table 5 Patients according to risk factors and complementary tests for CMPA.

Variable	Patients	
	No.	%*
Risk factors		
Caesarean delivery	5	50
Personal atopy	4	40
Familial atopy	3	30
Complementary exams		
Complete blood count	10	100
Absolute eosinophil count	4	40
Serum IgE determination	2	20
IgE quantification	1	10

Fountain: Medical records.
*Total patients with CMPA=10.

Discussion

The result obtained regarding the predominance of the female sex with 6 patients, from 1 to 6 months with 60%, coincides with that obtained by Dr. Mehaudy R et al. (14) with 55.2% preponderance in females and average age of diagnosis of 3.6 months. Similarly, Domínguez García et al. (10) women represented 86.7% of the total. However, Cuevas Rivas et al. (6) in their research the male sex was the most predominant (61.3%). Result that differs from those of the present study.

Regarding age, the authors believe that the predominance in infants is due to the relative immaturity of their immune system, poor antigenic experience, not being exclusively

breastfed until six months of age, and protein-energy malnutrition, all of which makes them more vulnerable to certain immuno-allergic processes.

The most common length of stay was less than 5 days. Regarding this finding, no literature was found to establish a comparison; researchers emphasize other variables. However, the authors of this study consider it valid, highlighting early discharge after not starting and/or completing the laboratory tests required for the disease. To a lesser extent, follow-up to the diagnostic test for tolerance to hydrolyzed milk was considered.

There was a predominance of malnourished patients, which has been explained by this group's vulnerability to immunological disorders. Malnutrition resulting from multiple crises could be due to underdiagnosis or improper management of the disease.

The most common clinical manifestations presented by infants were diarrhea and skin lesions. Díaz Gutiérrez, in his research, reflects that skin lesions such as local or generalized urticaria, angioedema, and diarrhea are some of the immediate reactions suffered by patients with CMPA. (15)

Canto Martínez and Alonso Rubio (16) in their study, 31% of patients presented cutaneous clinical manifestations; while 83.3% suffered digestive symptoms, among the most important of which were diarrhea and vomiting.

The clinical manifestations of CMPA are varied, and it can affect different organ systems, such as the skin, digestive system, and respiratory system; and cause skin rashes, eczema, vomiting, diarrhea, colic, wheezing, or excessive crying. Late-onset symptoms are predominantly gastrointestinal, and include three syndromes: digestive proctocolitis, enteropathy, and cow's milk protein-induced enterocolitis. (16)

It was observed that a minority of children were exclusively breastfed until 6 months of age, which translates to a higher risk of CMPA, combined with the introduction of new foods into the diet. This is consistent with the study by the Spanish Society of Pediatrics regarding the advantages of EBF. It also coincides with a study conducted at the Medical

University of Costa Rica in 2018, which showed that 89% of children under 6 months of age who were not breastfed developed the disease. (17)

Other studies show that children under 3 months of age can develop the disease even if they are exclusively breastfed, which is consistent with the present study in two of the patients studied. (18)

Regarding the predominance of cesarean section as a risk factor, a study by González Hernández et al. (19) suggests a correspondence between colonization by Clostridium (cesarean section) and Bifidobacteria (vaginal route) with the development of the disease: higher prevalence in dystocic births, Clostridium with increased predisposition in 65% of patients in their study.

Epidemiological data on CMPA in Argentina are limited. Mehaudy et al. (14) in their 11-year study showed a prevalence of 0.8%; diagnosis of the disease increased over time, changing from 0.4% in 2004 to 1.2% in 2014; 55.2% were girls, and the average age at diagnosis was 3.6 months. 55.8% of infants were born by cesarean section. The predominant onset symptoms were bloody stools (41.4%); IgE-mediated symptoms accounted for 27.6%, and 68.7% of these symptoms began after the start of breastfeeding.

Complementary tests include a complete blood count, which may show anemia with eosinophilia, an absolute eosinophil count, and immunoglobulin determination, primarily IgE, which, although not specific for the diagnosis, is helpful in differentiating between atopic and non-atopic subjects.

The prognosis is good if tolerance is complete at five years of age in cases of non-IgE-mediated allergy, and 80% in cases of IgE-mediated allergy. Poor prognostic factors include: early onset with intense symptoms, sensitization to casein and other foods, and symptomatic exposure to quantities of milk less than 10 mL. (20)

The authors consider the fundamental pillars of treatment to be the elimination of fluids

and their derivatives. We recommend that, if breastfeeding, the mother avoid dairy products; and if formula-feeding, she should receive hydrolyzed milk formula; or, for children older than six months and without digestive symptoms, soy formulas.

Cuba has produced few studies related to the topic, only three in the last five years; this is insufficient to establish comparisons. The authors reflect that, after assessing the healthcare activity at the "Hermanos Cordové" Children's Hospital in Manzanillo from a day-to-day perspective, there is no unified opinion on the true impact of CMPA within the complex healthcare process provided by the institution. At the administrative level, there is empirical argumentation that places the disease as a health problem that deserves prompt and special attention.

Conclusions

In the study, female sex and ages between one and six months were the most prevalent. Diarrhea and skin lesions were the most common clinical manifestations in patients with cow's milk protein allergy. Malnourished infants, those on formula, and those with a history of cesarean delivery were more likely to suffer from this disease.

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Conflict of interest:

The authors declare no conflicts of interest. They certify the authenticity of their declared authorship and the originality of the text.

Authorship contribution

Mirtha Ofelia Rondón Peña: conceptualization, data curation, formal analysis, research, methodology, project administration, supervision, validation, writing - original draft and writing - review and editing.

Delmis Esther Montero Verdecia: conceptualization, data curation, formal analysis, research, methodology, validation, writing-original draft and writing-review and editing.

Suzanne Santiesteban Puerta: conceptualization, data curation, formal analysis, research, validation, writing - original draft and writing - review and editing.

Katherine de la Caridad Garrido Benítez: conceptualization, data curation, formal analysis, research supervision, methodology, writing-original draft and writing-review and editing.

Yunior Meriño Pompa: research, methodology, writing - original draft and writing - revision and editing.

Katia Avalo Sánchez: methodology, writing-original draft and writing-revision and editing.