

Clinical Management of Cow's Milk Protein Allergy in Primary Health Care

Manejo Clínico da Alergia à Proteína do Leite de Vaca na Atenção Primária Em Saúde

Manejo Clínico de la Alergia a las Proteínas de la Leche de Vaca en la Atención Primaria de Salud

RESUMO

Introdução: A prevenção primária em saúde envolve estratégias destinadas a evitar o desenvolvimento da alergia desde a infância, como no caso da alergia à proteína do leite de vaca (APLV) que afeta de 2 a 3% das crianças no mundo. **Objetivo:** Este artigo destaca o papel da Atenção Primária à Saúde (APS) como elemento central do cuidado longitudinal. **Metodologia:** Trata-se de revisão de literatura baseada nas diretrizes para tratamento da APLV do Ministério da Saúde, no guideline "An update to the Milk Allergy in Primary Care guideline" e em publicações indexadas na base de dados PubMed até março de 2024. **Resultados:** Além do PCDT e do MAP Guideline, os profissionais de saúde da SES/DF têm como referência técnica o Protocolo de Manejo Nutricional na Alergia às Proteínas do Leite de Vaca para Crianças Menores de 2 Anos de Idade, que orienta o diagnóstico e tratamento dessa condição. **Conclusão:** Evidente que o diagnóstico precoce, a falta de capacitação dos profissionais de saúde, as barreiras econômicas e a resistência cultural, dificultam o acesso e a adesão às fórmulas e ao tratamento nutricional.

DESCRIPTORIOS: Hipersensibilidade a Leite; Prevenção Primária; Prevenção Secundária; Atenção Primária em saúde

ABSTRACT

Introduction: Primary prevention in health involves strategies aimed at avoiding the development of allergy from childhood, as in the case of cow's milk protein allergy (CMPA), which affects 2 to 3% of children worldwide. **Objective:** This article highlights the role of Primary Health Care (PHC) as a central element of longitudinal care. **Methodology:** This is a literature review based on the guidelines for the treatment of CMPA of the Ministry of Health, in the guideline "An update to the Milk Allergy In Primary Care guideline" and in publications indexed in the PubMed database until March 2024. **Results:** In addition to the PCDT and the MAP Guideline, the health professionals of the SES/DF have as a technical reference the Nutritional Management Protocol for Allergy to Cow's Milk Proteins for Children Under 2 Years of Age, which guides the diagnosis and treatment of this condition. **Conclusion:** It is evident that early diagnosis, lack of training of health professionals, economic barriers and cultural resistance make access and adherence to formulas and nutritional treatment difficult.

DESCRIPTORS: Milk Hypersensitivity; Management; Primary Prevention; Secondary Prevention; Primary Health Care

RESUMEN

Introducción: La prevención primaria en salud implica estrategias diseñadas para prevenir el desarrollo de alergias desde la infancia, como es el caso de la alergia a la proteína de la leche de vaca (APLV), que afecta del 2 al 3% de los niños en todo el mundo. **Objetivo:** Este artículo destaca el papel de la Atención Primaria de Salud (APS) como elemento central de la atención longitudinal. **Metodología:** Se trata de una revisión de la literatura basada en las guías para el tratamiento de la APLV del Ministerio de Salud, la guía "Una actualización de la guía de Alergia a la Leche en Atención Primaria" y publicaciones indexadas en la base de datos PubMed hasta marzo de 2024. **Resultados:** Además de la Guía PCDT y MAP, los profesionales de la salud de la SES/DF tienen como referencia técnica el Protocolo de Manejo Nutricional de la Alergia a la Proteína de la Leche de Vaca para Niños Menores de 2 Años. de Edad, que orienta el diagnóstico y tratamiento de esta condición. **Conclusión:** Es evidente que el diagnóstico temprano, la falta de capacitación de los profesionales de la salud, las barreras económicas y las resistencias culturales dificultan el acceso y la adherencia a las fórmulas y al tratamiento nutricional.

DESCRIPTORIOS: Hipersensibilidad a la leche; Prevención Primaria; Prevención Secundaria; Atención primaria de salud

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INTRODUCTION

Cow's milk protein allergy (CMPA) is one of the most common food allergies in childhood, affecting approximately 2 to 3% of children worldwide. ⁽¹⁾ This immunological condition occurs when the immune system overreacts to proteins present in cow's milk, leading to a series of symptoms that can range from mild to severe, including skin, gastrointestinal and respiratory manifestations. ⁽²⁾ In this context, primary prevention of CMPA involves strategies aimed at preventing the development of the allergy from the first days of life. ⁽¹⁾ Among the most studied and recommended approaches is exclusive breastfeeding for the first six months, which offers immunological protection and can help in the development of tolerance to food proteins. ⁽³⁾

The controlled and supervised introduction of solid foods, including dairy

products, from six months of age, as well as the introduction of cow's milk after one year, adequate prenatal care and breastfeeding until two years of age can also be protective. ⁽⁴⁾ Furthermore, during prenatal care, medical care and nutritional monitoring not only ensure the well-being of the pregnant woman, but also directly influence the baby's immunological development. ⁽¹⁾ During prenatal consultations, health professionals have the opportunity to identify risk factors for the development of allergies, such as a family history of allergies, providing evidence-based guidance on maternal nutrition. ⁽³⁾

Secondary prevention of CMPA aims at early identification of the condition, followed by strict dietary management to avoid exposure to cow's milk proteins. ⁽¹⁾ This includes the adoption of strict exclusion diets, where all products containing cow's milk are eliminated from the diet of the child and mother, and can

be replaced by special formulas that ensure adequate nutrition for the patient. ⁽¹⁾⁽³⁾ Careful reading of food labels and ongoing education of parents and caregivers are essential to avoid accidental ingestion of allergens. In addition, collaboration with nutritionists helps to ensure that the child's diet is balanced and meets nutritional needs, avoiding deficiencies that may compromise their growth and development. ⁽³⁾

In this context, specialized formulas play a fundamental role in the safe nutrition of infants and young children with CMPA. ⁽⁵⁾ Unlike formulas based on extensively hydrolyzed proteins, formulas that contain free amino acids are free of milk proteins and do not cause allergic reactions, examples include Neocate, Neoforte and Nutramigen. Other options include plant-based formulas, such as soy milk, plant-based milks such as almond, rice, oat and coconut milks, but they are not considered the first choice

for CMPA, due to the severity of the disease, the child's age and the adverse effects of the formulas.⁽⁵⁾

This study aims to clarify the management strategies for patients diagnosed with CMPA, with an emphasis on the description of nutritional formulas provided by the Unified Health System (SUS). In addition, it seeks to highlight the role of Primary Health Care (PHC) as a central element of longitudinal care, contributing to a comprehensive approach that favors the well-being and quality of life of these patients and their families.

METHOD

This is a literature review based on the guidelines for the treatment of CMPA from the Ministry of Health, in the guideline "An update to the Milk Allergy in Primary Care guideline" and in publications indexed in the PubMed database, carried out through the search ("Milk Hypersensitivity/prevention and control" [Mesh] OR "Milk Hypersensitivity/therapy" [Mesh]), in March 2024, using as filters the types of articles clinical trial, randomized clinical trial, reviews, systematic reviews and meta-analyses, with free access, published in the last 5 years, in English, Portuguese and Spanish.

The exclusion criteria used in the selection of articles were studies that addressed various food allergies not exclusively to cow's milk protein or syndromes associated with CMPA, studies in animals, in vitro or in populations over 2 years of age, and those that did not address the scope of this review that focuses on management tools in both primary and secondary prevention of CMPA.

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RESULTS AND DISCUSSION

1. Primary prevention of CMPA

1.1 Exclusive breastfeeding

According to the Nutritional Management Protocol for Cow's Milk Protein Allergy of the Federal District Health Department (SES-DF) of 2024⁽⁶⁾, both IgE-mediated and non-IgE-mediated allergies in all their degrees of intensity occur in approximately 5% of exclusively breastfed babies, and in these cases it is recommended to exclude milk protein sources from the nursing mother's diet for 2 to 4 weeks together with daily oral supplementation with calcium and vitamin D.^(2,7)

Breastfeeding should always be encouraged as the child's main source of nutrition, especially before 6 months of age, and its discontinuation is rarely recommended, as in cases of HIV-positive mothers or regular users of alcohol and drugs.^(2,8)

In cases of symptoms in babies who use infant formula or mixed feeding (breastfeeding combined with formula), the first recommendation is exclusive breastfeeding with observation of the response, and only if this fails is the use of special formulas indicated.⁽⁷⁾

It is worth noting that establishing exclusive breastfeeding in patients who already use formula or mixed feeding is extremely difficult, since factors such as low breast milk production, inadequate acceptance by the infant, and the complexities of the postpartum period may be involved.

The evidence on the impact of the use of cow's milk-based infant formulas in maternity and nursery settings on the risk of developing cow's milk allergy is

mixed and complex. A randomized trial published in *JAMA Pediatrics* suggests that avoiding cow's milk formula supplementation in the first few days of life may reduce the risk of sensitization to cow's milk protein and food allergies, including CMPA.⁽⁹⁾ This study indicated that cow's milk formula supplementation increased the risk of cow's milk sensitization compared with exclusive breastfeeding.

In contrast, a case-control study found that the introduction of complementary bottles in maternity settings was associated with an increased risk of CMPA in infants.⁽¹⁰⁾ This study highlighted that early introduction of cow's milk formula bottles may be an independent risk factor for the development of CMPA and other food allergies. Additionally, a systematic review and meta-analysis evaluated the use of partially or extensively hydrolyzed formulas compared with cow's milk formulas and breast milk. The evidence was inconclusive regarding the effectiveness of these hydrolyzed formulas in preventing allergic diseases, including cow's milk allergy, compared with cow's milk formula.⁽¹¹⁾

1.2 Elimination and reintroduction of cow's milk

After implementing a diet based on the elimination of cow's milk proteins, it is essential to reintroduce them into the diet in order to observe the recurrence of symptoms and confirm the diagnosis. Once the diagnosis of CMPA has been established, it is recommended to completely eliminate cow's milk proteins for at least 6 months, and until the child is between 9 and 12 months old. After this period of exclusion, supervised reintroduction can be performed to check whether tolerance has been achieved.⁽⁷⁾

During this period, the patient should be recommended to undergo the Oral Provocation Test (OPT), the gold standard, which consists of progressively offering the allergenic substance and placebo, at intervals, to identify remaining allergic reactions. OPT is indicated for

patients who no longer have symptoms after the exclusion of allergens from the diet, and prior to reintroduction.⁽¹²⁾

1.3 Food introduction

According to the recommendations of the World Health Organization (WHO), the introduction of solid foods should begin at six months of age. In the case of children with cow's milk protein allergy (CMPA), the guidelines analyzed in this study do not indicate additional restrictions in relation to healthy children, allowing the inclusion of other sources of protein, such as eggs, beef and fish, without specific contraindications.⁽²⁾

In addition, it is essential that families pay attention to the detailed reading of the labels of processed foods, in order to identify possible traces of the allergen in their composition. The consumption of foods prepared by third parties also requires caution, due to the risk of cross-contamination or inadvertent use of ingredients containing cow's milk proteins.

2. Secondary prevention of CMPA

The treatment of CMPA is based on the complete elimination of cow's milk protein from the diet of the child and, when applicable, of the lactating mother, prioritizing the maintenance of exclusive or continued breastfeeding, unless medically contraindicated. When breastfeeding is not possible, whether in children under 6 months of age or in infants between 6 and 24 months who are no longer breastfed, the use of special nutritional formulas is indicated to meet the nutritional needs of this critical stage of development.

The nutritional formulas available for the management of CMPA include those based on extensively hydrolyzed proteins (with or without lactose), formulas based on free amino acids and, in some specific cases, formulas based on soy protein. These alternatives, incorporated into the SUS by Ordinance No. 67, of November 23rd, 2018, guarantee

access to children aged 0 to 24 months with CMPA treated in the PHC, as recommended by the National Commission for the Incorporation of Technologies into the SUS (CONITEC).⁽¹³⁾ The choice of the most appropriate formula must consider the severity of the allergy, the child's age and possible comorbidities.

The use of these formulas is supported by scientific evidence, which demonstrates significant clinical improvement in symptoms between one and three weeks after starting treatment. It is therefore recommended that the prescribed formula be maintained for a minimum period of two weeks before assessing the need for replacement, always under medical supervision.⁽²⁾

In addition, nutritional management requires constant monitoring, including careful reading of labels on processed foods to identify possible allergens and the adoption of preventive measures in situations where food prepared by third parties is consumed.

2.1 Extensively hydrolyzed formulas (eHF)

Formulas based on extensively hydrolyzed proteins are widely indicated for the management of mild to moderate cases of non-IgE-mediated CMPA and in IgE-mediated cases, especially when the patient was previously using infant formulas or was not exclusively breastfed.⁽⁷⁾ With a tolerability rate of over 90%, these formulas are considered the first choice for children under 24 months of age with non-IgE-mediated CMPA and for infants under six months of age with IgE-mediated CMPA, provided that clinical improvement is observed after treatment is initiated.⁽²⁾

Among the options available on the SUS, the **Pregomin Pepti** formula, manufactured by Nutricia Cuijk Bv, stands out, as it is highly tolerable and has an average cost of R\$215.00 per can on the private market, with an estimated duration of approximately two weeks of use. Another formula provided by the

SUS is **Aptamil Pepti**, from Danone Nutricia, which contains prebiotics, long-chain fatty acids (LcPUFAs), such as DHA (docosahexaenoic) and ARA (arachidonic), in addition to nucleotides in its composition. On the general market, the average price of this formula is R\$135.00, also with a duration of approximately two weeks per can. Both formulas are widely used in the management of CMPA due to their efficacy and balanced nutritional composition.⁽⁸⁾

2.2 Formulas based on free amino acids (FAA)

FAA and eHF are the main nutritional options in the management of CMPA. While eHF are widely used as the first choice due to their high tolerability rate, FAA represent the only completely "non-allergenic" formulation, being indicated in more restricted and specific situations, corresponding to approximately 5-10% of cases.⁽⁸⁾ FAA are recommended mainly in cases of intolerance or clinical ineffectiveness of eHF, in cases of severe non-IgE-mediated CMPA in children under 24 months, with a high risk of anaphylactic reactions, or in cases of severe malabsorption with nutritional impairment.^(2,7)

Furthermore, FAAs are preferred as the first choice in the treatment of CMPA-related syndromes, such as food protein-induced enterocolitis, allergic eosinophilic esophagitis, chronic lung disease induced by cow's milk (Heiner syndrome), and enteropathy with malnutrition.⁽⁸⁾ These conditions require a more specific and safe formulation to avoid exposure to allergenic proteins and ensure adequate nutritional support.

After clinical stabilization in cases of severe allergies, it is recommended, when feasible, to replace FAAs with extensively hydrolyzed formulas (eHF) or soy-based formulas (SBF), according to the clinical evolution and tolerance of the patient. However, the lack of improvement after two weeks of FAA use should lead to a diagnostic reassessment, with the suspension of the formula and

referral of the patient for specialized evaluation. (2)

Among the options available on the market, **Neocate LCP**, manufactured by Danone Nutricia, stands out as a powdered infant formula composed of free amino acids, glucose syrup, vegetable oils and medium-chain triglycerides (MCT). With an average price of R\$240.00 on the private market, this formula can be accessed through the SUS, and in the Federal District through the Enteral and Home Nutritional Treatment Program (PTNED - *Programa de Tratamento Nutricional Enteral e Domiciliar*).

2.3 Formulas of plant origin

The soy-based formulas currently available have been improved to correct nutritional deficiencies observed in previous formulations. These formulas are supplemented with amino acids, iron, zinc, calcium and phosphorus, and also have low levels of phytates, compounds that interfere with the absorption of essential nutrients. (14)

However, their use has some restrictions due to concerns related to the possible hormonal effects of isoflavones present in soy and the consumption of transgenic products. In addition, these formulas are less tolerable in cases of allergies compared to non-vegetable formulas, which is why they are contraindicated for children under six months of age. (14)

According to the Milk Allergy in Primary Care Guideline (MAP), soy-based formulas (SBF) can be considered a first option for children between six and 24 months of age, as long as they do not present sensitivity detected by the IgE test. (7) However, due to the high incidence of adverse effects, these formulas are contraindicated for infants under six months of age and for those at high risk of anaphylaxis. (2)

Another alternative of plant origin are formulas based on hydrolyzed rice proteins, which offer advantages such as lower allergenic potential and absence of phytoestrogens. These characteristics

make these formulas a second option for cases of intolerance to eHF or in severe cases of CMPA. (14) Although their use is recognized in some countries, in Brazil rice-based formulas still do not have a formal consensus recommendation by the Brazilian Consensus on Food Allergy. (8)

2.4 Use of probiotics in CMPA

Probiotics, defined as live microorganisms that, when administered in adequate amounts, appear to confer health benefits to the host, have shown promise in the management of CMPA, although scientific evidence is lacking. Their theoretical efficacy is related to several biological mechanisms that contribute to the reduction of intestinal inflammation and allergic reactions. Among these mechanisms, the most notable are the modulation of the expression of tight junctions in the intestinal barrier, promoting mucosal integrity, the balance between Th1 and Th2 immune responses, which results in the reduction of pro-inflammatory cytokines IL-4 and IL-5, and the increase in the secretion of regulatory T cells and the production of IgA, strengthening intestinal immunity. (13)

The development of the intestinal microbiota is particularly significant in the first years of life, a period in which microbial colonization reaches an estimated total of up to 1015 microorganisms, distributed among more than 1,000 distinct strains in the gastrointestinal tract. This microbial diversity plays essential roles in human health, such as regulating the digestive process, developing and modulating the immune system, and controlling the growth and differentiation of intestinal epithelial cells. Adequate microbial exposure during this phase contributes to the formation of a balanced microbiota, capable of preventing immunological imbalances that can aggravate allergy symptoms. (15)

In this sense, the use of probiotics in the management of CMPA in children has been the subject of investigation,

with some studies suggesting potential benefits. A systematic review indicates that probiotic supplementation may be associated with an earlier acquisition of tolerance to cow's milk protein in children with CMPA, although the evidence is of low quality and influenced by a large study. (16) No adverse effects related to probiotics were observed.

Furthermore, another study demonstrated that extensively hydrolyzed casein formula containing *Lactobacillus rhamnosus* GG can reduce the occurrence of other allergic manifestations and accelerate the development of oral tolerance in children with IgE-mediated CMPA. (17) This finding suggests a potential role for probiotics in modulating the immune response and promoting tolerance.

In contrast, Hol et al. found no significant difference in the acquisition of tolerance to cow's milk between groups receiving probiotics and placebo, indicating that the effects may vary depending on the probiotic strain used and the study design. (18)

Although there is evidence to suggest that probiotics may aid in the acquisition of tolerance to cow's milk protein in children with CMPA, the quality of the evidence is variable and more well-designed studies are needed to confirm these findings and determine the most effective probiotic strains.

3. Role of PHC in the clinical management of CMPA

The Clinical Protocol and Therapeutic Guidelines (PCDT - *Protocolo Clínico e Diretrizes Terapêuticas*) for CMPA, published in 2022 by CONITEC, presents comprehensive recommendations on the diagnosis, treatment, and monitoring of individuals with CMPA within the scope of the SUS. This protocol aims to standardize care at all levels of health care, ensuring a systematic and evidence-based approach to the management of the condition. (2)

According to the PCDT, the management of children with CMPA can

be carried out both in PHC and in specialized care referral centers. PHC plays a central role, being responsible for the initial identification of clinical manifestations, guidance for families, and longitudinal monitoring of the patient. Based on the principles of comprehensiveness, longitudinality, and first access, PHC enables a continuous and coordinated approach, which is essential for the successful management of CMPA. In more complex cases, such as severe or refractory allergies, the protocol guides referral to specialized centers, ensuring the necessary support in situations that require advanced diagnostic or therapeutic resources.⁽²⁾

The *Milk Allergy in Primary Care* (MAP) Guideline was initially developed in the United Kingdom in 2013 as a practical tool to guide PHC professionals in the diagnosis and management of CMPA. Based on scientific evidence, the MAP addresses critical issues such as early identification of signs and symptoms, differentiation between IgE-mediated and non-IgE-mediated CMPA, and appropriate nutritional management, including the recommendation of special formulas and guidance on food reintroduction. The guideline was subsequently updated with contributions from experts from other continents, expanding its applicability and validating it as an international tool.⁽⁷⁾ The main components of the MAP include: structured diagnosis, dietary management, food reintroduction, and support for longitudinal care.

With these components, the MAP Guideline provides robust, evidence-based support, enabling PHC professionals to manage CMPA in an efficient and integrated manner. Its comprehensiveness and practicality make it an essential resource for optimizing the management of this condition and improving clinical outcomes in diverse populations.

In addition to the PCDT and the MAP Guideline, SES/DF health professionals have as a technical reference the Nutritional Management Protocol

for Cow's Milk Protein Allergy in Children Under 2 Years of Age, a document that guides the diagnosis and nutritional treatment of this condition. This protocol, launched in 2022, is specific to the context of the SUS in the DF and covers aspects such as the appropriate selection of infant formulas and clinical monitoring of children with CMPA, highlighting the importance of a careful diagnosis, based on clear clinical criteria and provocation tests, to avoid unnecessary treatments or underdiagnosis. Regarding nutritional management, it recommends the use of eHF as the first choice in most cases of CMPA, except in specific situations that require the use of FAA.⁽⁶⁾

Within the scope of SES-DF, the formulas are made available by SUS in different presentations, such as Pregomin Pepti, Aptamil Pepti and Neocate, reiterated in 2021 by a technical opinion from the Technical Support Center for the Judiciary of the Court of Justice of the Federal District and Territories, addressing the indication and use of the formulas. This document aims to assist judicial decisions related to the dispensing of these formulas by SUS, based on scientific evidence and public health guidelines. The opinion reinforces that, according to the Constitution, the provision of formulas by SUS must be guaranteed to meet the health needs of patients who meet the clinical criteria.

In the aforementioned documents, the PHC is described as co-responsible for the continuous monitoring of patients with CMPA. It is recommended that these patients be clinically monitored every three months, with specific assessments every 6 to 12 months to check for the development of tolerance to cow's milk protein. Proof of persistence of the allergy within this interval is a requirement for the patient to remain in the government program of the SES-DF, which is responsible for dispensing special nutritional formulas.⁽²⁾

Even after the PTNED has stopped providing infant formulas, upon reaching 2 years of age, it is essential that the

APS maintain continuous monitoring of these patients in conjunction with Secondary Care, when appropriate. This monitoring should be carried out regardless of the need for nutritional supplementation, with a focus on maintaining comprehensive care, monitoring nutritional status, and supporting the development of allergic tolerance, promoting health and preventing possible long-term complications.⁽⁸⁾

CONCLUSION

The importance of primary and secondary prevention in CMPA lies not only in minimizing the risk of developing and worsening the allergy, but also in promoting a better long-term prognosis, facilitating a healthy and less restrictive life. Adopting these strategies in a broad and coordinated manner can result in a significant reduction in the prevalence and severity of CMPA, emphasizing the need for public health and education policies that support these prevention efforts.

Exclusive breastfeeding, the strict elimination of cow's milk proteins, and the introduction of special formulas are essential pillars to ensure the well-being of children with CMPA. Some challenges, such as early diagnosis and economic barriers, hinder access to and adherence to formulas, which hinders the development of longitudinality.

Therefore, the clinical management of CMPA permeates the field of private care concurrently with PHC, while the clinical experience shown in the study demonstrates that there is bias in diagnosis and barriers exacerbated by the lack of consensus on the use of specific diagnostic tests, such as skin tests or serum IgE. The difficulties of management also come up against the (in)availability and access not only to special formulas.

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