



ORIGINAL ARTICLE

Faecal calprotectin as an aid to the diagnosis of non-IgE mediated cow's milk protein allergy<sup>☆,☆☆</sup>



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KEYWORDS

Faecal calprotectin;  
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Abstract

**Introduction:** The aim of the study was to assess the use of faecal calprotectin (FCP) in infants with signs and symptoms of non-IgE-mediated cow's milk protein allergy (CMA) for both diagnosis and prediction of clinical response at the time of withdrawal of milk proteins.

**Patients and methods:** A one year prospective study was conducted on 82 infants between 1 and 12 months of age in the Eastern area of Málaga-Axarquía, of whom 40 of them had been diagnosed with non-IgE-mediated CMA (with suggestive symptoms and positive response to milk withdrawal), 12 not diagnosed with CMA, and 30 of them were the control group. FCP was measured at three different times: time of diagnosis, and one and three months later. ANOVA for repeated measures, nominal logistic regression and ROC curves were prepared using the SPSS.20 package and Medcalc.

**Results:** Differences between diagnostic and control groups were assessed: there was a statistically significant relationship ( $P < .0001$ ) between high FCP levels and infants suffering CMA, as well as the levels at time of diagnosis, 1 and 3 months ( $P < .001$ ). A ROC curve was constructed between FCP levels and diagnosis of CMA, with 138  $\mu\text{g/g}$ , with the best cut-off being with an area under the curve of 0.89. However, it is only 0.68 to predict a clinical response.

**Conclusions:** FCP levels lower than 138  $\mu\text{g/g}$  could be useful to rule out non-IgE-mediated CMA diagnosis. Calprotectin is not a good test to predict clinical response to milk withdrawal.

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**PALABRAS CLAVE**

Calprotectina fecal;  
Alergia a proteínas de  
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Inmunoglobulina E

## Calprotectina fecal como apoyo al diagnóstico en la alergia a las proteínas de leche de vaca no IgE mediada

### Resumen

**Introducción:** El objetivo del estudio es evaluar la utilidad de la calprotectina fecal (CPF) en lactantes con sospecha de alergia a las proteínas de leche de vaca (APLV) no IgE mediada tanto para el diagnóstico como para predecir la respuesta clínica a la supresión láctea.

**Pacientes y métodos:** Estudio prospectivo, de un año de duración, incluyendo 82 lactantes entre 1-12 meses en el Área Este de Málaga-Axarquía. De ellos: 40 se diagnostican de APLV no IgE mediada (síntomas compatibles y respuesta positiva a la supresión láctea), 12 no se confirma APLV y además 30 como grupo control. Se determina CPF al diagnóstico, al mes y a los 3 meses. El análisis estadístico realizado fue ANOVA para medidas repetidas, regresión logística nominal y curvas ROC utilizando los programas SPSS 20 y Medcalc.

**Resultados:** Se analizan diferencias entre los grupos y se objetiva relación estadísticamente significativa entre cifras elevadas de CPF y padecer APLV ( $p < 0,0001$ ). También se constata relación estadísticamente significativa entre cifras de CPF al diagnóstico, al mes y a los 3 meses ( $p < 0,001$ ). Finalmente se realiza una curva ROC entre cifras de CPF y diagnóstico de APLV resultando una área bajo la curva de 0,89 y siendo 138  $\mu\text{g/g}$  el mejor nivel de corte. Sin embargo, para predecir respuesta clínica este valor es únicamente de 0,68.

**Conclusiones:** Cifras de CPF inferiores a 138  $\mu\text{g/g}$  podrían ser útiles para descartar el diagnóstico de APLV no IgE mediada. La CPF no es un buen test para predecir respuesta clínica a la exclusión láctea.

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## Introduction

Cow's milk protein allergy (CMPA) is a frequent problem with an estimated prevalence of 2%–7.5%.<sup>1</sup> It is classified into immunoglobulin E (IgE)-mediated and non-IgE-mediated allergy. IgE-mediated CMPA usually manifests with cutaneous and respiratory symptoms, such as urticaria, angioedema and anaphylaxis following ingestion of cow's milk. It is diagnosed based on a thorough history taking and confirmed by means of specific IgE determination or a skin prick test and a subsequent challenge. The main symptoms in non-IgE-mediated CMPA are digestive, such as diarrhoea, vomiting, bloody stools, irritability or failure to thrive. Since allergy is not mediated by IgE in this group of patients, specific IgE or skin prick tests will not be helpful, and when it is suspected, the only diagnostic tool is the elimination of cow's milk protein from the diet for four to six weeks to watch for the resolution of symptoms. The elimination of cow's milk protein entails the use of extensively hydrolysed protein-based formulas that carry a significant economic cost and, in many instances, are rejected by the infant and the family due to their unpleasant taste and smell.<sup>1-7</sup>

Faecal calprotectin (FCP) is a protein that is mostly found in the cytoplasm of neutrophils, although it can also be expressed in the membrane of activated monocytes and macrophages. Consequently, its levels are elevated in the presence of infectious and/or inflammatory processes. In recent years, FCP has been increasingly used as a noninvasive marker for the differential diagnosis of organic and functional disease.<sup>8-12</sup>

Since the diagnosis of non-IgE-mediated CMPA is based on clinical suspicion and the elimination of cow's milk protein

from the diet with evaluation of the clinical response, we decided to assess the usefulness of FCP in infants with signs and symptoms suggestive of non-IgE-mediated CMPA for the purposes of diagnosis and to predict the clinical response to a dairy-free diet.

## Patients and methods

We conducted a prospective study of one year's duration. We included 82 infants aged 1–12 months that received care at the outpatient paediatrics clinic of the Hospital de la Axarquía in the Eastern Malaga Health Management Area in Spain.

## Clinical aspects

**Inclusion criteria:** infants aged 1–12 months presenting with symptoms compatible with non-IgE mediated CMPA such as diarrhoea, vomiting, bloody stools, irritability and/or failure to thrive.<sup>1,2</sup> We included 52 infants that presented one or more of these symptoms and were referred from Primary Care for participation in the study.

**Exclusion criteria:** babies aged less than 1 month or more than 12 months, IgE-mediated CMPA (verified by determination of total IgE and/or skin prick test). We also excluded patients with infectious diseases confirmed by stool or urine culture, born preterm, or with an underlying chronic disease.

Fifty-two patients met the inclusion criteria, so a sample was collected from them for FCP determination and cow's milk protein eliminated from their diets, substituting an

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