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## ORIGINAL ARTICLE

# Accuracy of serum IgE concentrations and papule diameter in the diagnosis of cow's milk allergy<sup>☆,☆☆</sup>

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### KEYWORDS

Milk hypersensitivity;  
Accuracy;  
Child;  
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### Abstract

**Objective:** To compare serum concentrations of specific IgE and mean papule diameters induced in the immediate skin reactivity test with cow's milk (CM) and its fractions with results of the oral challenge test (OCT), and to establish cutoff points capable of predicting clinical reactivity to CM in patients treated at a referral service.

**Methods:** One hundred and twenty-two children (median of 17 months) with a history of immediate reactions to CM and presence of specific IgE for CM and/or its fractions (positive skin and/or IgE serum tests) were submitted to open OCT with CM.

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<sup>☆☆</sup> Study carried out at Universidade Federal de São Paulo (UNIFESP), Escola Paulista de Medicina, São Paulo, SP; and Universidade Federal de Sergipe, Aracaju, SE, Brazil.

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**Results:** The OCT was positive in 59.8% of the children, 49% of whom were males. Serum levels of specific IgE, as well as mean CM papule diameters, were significantly higher in allergic patients (medians: 3.39 kUA/L vs. 1.16 kUA/L, 2.5 mm vs. 0 mm). The optimal cutoff points (Youden's index) of serum IgE specific for CM and its fractions capable of predicting CM reactivity (positive OCT) were: 5.17 kUA/L for CM, 0.95 kUA/L for  $\alpha$ -lactalbumin, 0.82 kUA/L for  $\beta$ -lactoglobulin, and 0.72 kUA/L for casein, whereas for papule diameters the cutoff points were 3.5 mm for CM and 6.5 mm, 9.0 mm, and 3.0 mm for the  $\alpha$ -lactalbumin,  $\beta$ -lactoglobulin, and casein fractions, respectively.

**Conclusions:** The cutoff points capable of predicting clinical reactivity to CM were: 5.17 kUA/L for serum-specific IgE and 3.5 mm for papule diameter measurement, values considered discriminatory for the diagnosis of CM allergy.

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## PALAVRAS-CHAVE

Hipersensibilidade a leite;  
Acurácia;  
Criança;  
Epidemiologia;  
Curva ROC

## Acurácia de concentrações de IgE séricas e de diâmetros de pápulas no diagnóstico de alergia ao leite de vaca

### Resumo

**Objetivo:** Comparar concentrações séricas de IgE específica e diâmetros médios das pápulas induzidas no teste cutâneo de leitura imediata com leite de vaca (LV) e suas frações com resultados do teste de provocação oral (TPO) e estabelecer pontos de corte, capazes de prever reatividade clínica ao LV em pacientes atendidos em um serviço de referência.

**Métodos:** Cento e vinte e duas crianças (mediana 17 meses), com história de reações imediatas ao LV e presença de IgE específicas para LV e/ou frações (testes cutâneos e/ou IgE sérica positivos) foram submetidas ao TPO aberto com LV.

**Resultados:** O TPO foi positivo em 59,8% das crianças, 49% eram do sexo masculino. Os níveis séricos de IgE específica, assim como os diâmetros médios das pápulas para LV, foram significativamente maiores nos alérgicos (medianas: 3,39kUA/L vs 1,16 kUA/L; 2,5mm vs 0mm). Os "pontos de corte ótimos" (Índice de Youden) das IgE séricas específicas para o LV e suas frações capazes de prever a reatividade ao LV (OCT positivo) foram: 5,17kUA/L para o LV, 0,95 kUA/L para  $\alpha$ -lactoalbumina, 0,82kUA/L para  $\beta$ -lactoglobulina e 0,72kUA/L para caseína e para os diâmetros de pápulas foram 3,5 mm para LV e 6,5 mm, 9,0 mm e 3,0 mm para as frações  $\alpha$ -lactoalbumina,  $\beta$ -lactoglobulina e caseína, respectivamente.

**Conclusões:** Os níveis de corte capazes de prever reatividade clínica ao LV foram: 5,17kUA/L para IgE sérica específica e 3,5 mm para a medida do diâmetro da pápula, valores considerados discriminatórios para o diagnóstico da alergia ao LV.

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## Introduction

Cow's milk protein allergy (CMPA) is defined as a reproducible, immunological adverse reaction to one or more cow's milk (CM) proteins.<sup>1</sup> It involves the participation of IgE immunoglobulins (IgE), cells (T-lymphocytes), or both.<sup>2</sup> It affects 2–3% of children, representing the most common food allergy in childhood.<sup>2</sup>

For the diagnosis of IgE-mediated CMPA, detailed clinical history and detection of IgE specific for allergens are important tools.<sup>3</sup> However, the double-blind, placebo-controlled oral challenge test (DBPCOCT), which consists in offering the food without the physician's or the patient's knowledge, continues to be considered the gold standard for the diagnosis of CMPA.<sup>4–7</sup> Nonetheless, it has disadvantages related to the time required for its performance, the costs involved,

and the need for an adequate physical structure and a multidisciplinary team, which are limiting factors for its broad use in clinical practice.<sup>7</sup>

Different values of serum-specific IgE and mean papule diameter in the immediate-reading skin test (IRST), from which the chance of having symptoms at the time of the OCT would be greater than 95% were established; however, the values found were not reproducible in different populations, and differences regarding ethnic-racial characteristics, age, dietary habits, clinical phenotypes, and technical conditions for IRST were presumed.<sup>8–15</sup>

The desire to minimize OCTs – with their inherent risks – together with the unavailability of an adequate universal cutoff point for all populations, motivated this study, whose objectives are: to compare serum concentrations of specific IgE and mean papule diameter induced by the IRST with CM and its fractions with OCT results, and to establish

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