IMPLEMENTATION OF HOME-BASED ORAL FOOD CHALLENGE IN CHILDREN WITH NON-IGE-MEDIATED COW'S MILK PROTEIN ALLERGY SAFETY AND FEASIBILITY

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ABSTRACT

This study aimed to evaluate the safety, feasibility, and diagnostic value of the slow, mainly home-based oral food challenge (OFC) protocol in children with non-IgE-mediated cow's milk allergy (CMA). A cross-sectional study was conducted on 51 children, mostly under 2 years old, examined at Children's Hospital 1 from July 2024 to July 2025. All participants underwent the slow-protocol OFC, starting with 30 mL of cow's milk at the hospital, followed by gradual dose increases of 30 mL every 2–3 days at home, under remote medical supervision. Results showed that 78.4% of children tolerated cow's milk again, while 21.6% had a positive OFC response, mainly presenting with mild to moderate gastrointestinal or skin symptoms. No severe adverse events were recorded. Symptoms appeared between day 2 and day 19 after dose escalation began; the median time from OFC initiation to final diagnosis was 28 days (IQR 20–30). The slow-protocol OFC conducted at home proved to be safe, feasible, and diagnostically valuable in pre-screened children, as the majority of those initially suspected of allergy were found to tolerate cow's milk after a period of elimination.

Keywords: *cow's milk allergy; non-IgE-mediated allergy; oral food challenge; home-based challenge.*

I. INTRODUCTION

Cow's milk allergy (CMA) is one of the most common food allergies in infants and young children, with a global prevalence of approximately 2-7.5% and an estimated 2.1% in children in Vietnam [1-3]. CMA can be IgE-mediated, non-IgE-mediated or mixed; among these, non-IgE-mediated forms typically have a delayed onset after exposure, manifesting primarily in the gastrointestinal tract and/or skin, with non-specific symptoms that are easily confused with functional gastrointestinal disorders [1,4-6].

The Oral Food Challenge (OFC) is the gold standard for the diagnosis of CMA. Hospital-based OFC has been widely implemented, but primarily for IgE-mediated cases [1,3,7-9]; its application for the non-IgE group remains challenging due to non-specific symptoms, delayed onset characteristics, and the lack of supportive biomarkers [4,6]. Overdiagnosis or prolonged elimination of cow's milk can lead to nutritional deficiencies and affect the quality of life of the child and family [1,10,11].

Recent guidelines from the World Allergy Organization (WAO), the DRACMA document (Diagnosis and Rationale for Action against Cow's Milk Allergy), and several recent studies have expanded the indications for OFC to the non-IgE-mediated CMA group, including home-

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based implementation under the supervision of medical personnel [1,4,6,12]. In Vietnam, there have been no published studies on the application of OFC for diagnosis and tolerance monitoring in children with non-IgE-mediated CMA. Children's Hospital 1 is currently the first unit to develop a clinical protocol to implement OFC for this target group.

Therefore, this study was conducted with the objective of evaluating the safety and feasibility of a slow-protocol OFC conducted mainly at home for children suspected of or diagnosed with non-IgE-mediated CMA, aiming to provide scientific evidence for the implementation of this method in pediatric clinical practice in Vietnam.

II. RESEARCH SUBJECTS - METHODS

2.1. Study design and setting

A descriptive cross-sectional study was conducted at Children's Hospital 1, Ho Chi Minh City, from July 2024 to July 2025.

2.2. Research subjects

Children < 16 years old, presenting at the allergy clinic with a diagnosis or suspicion of non-IgE-mediated CMA and indicated for OFC to evaluate allergic status or tolerance to cow's milk protein.

2.3. Inclusion and exclusion criteria

Children were included in the study if they belonged to one of two groups:

(1) *Suspected group:* Clinical symptoms suggestive of non-IgE-mediated CMA (mainly gastrointestinal and/or skin symptoms with delayed onset > 2 hours after cow's milk ingestion), clear improvement of symptoms after 2-4 weeks of cow's milk elimination, and a negative Skin Prick Test (SPT) with fresh cow's milk.

(2) *Tolerance assessment group (hereafter referred to as the tolerance group)*: Previously diagnosed with non-IgE-mediated CMA, having eliminated cow's milk for ≥ 6 months or aged ≥ 9 months, and a negative SPT with fresh cow's milk.

Exclusion criteria included children with clear IgE-mediated allergy manifestations (urticaria, anaphylaxis within 2 hours after milk ingestion), Food Protein-Induced Enterocolitis Syndrome (FPIES), uncontrolled asthma or severe respiratory disease, acute medical conditions or exacerbation of chronic diseases, or parents who did not consent/were unable to monitor the OFC at home.

2.4. OFC procedure

All children underwent the OFC according to the slow protocol of Children's Hospital 1, consisting of two phases:

- *Hospital-based phase:* each child received an initial dose of 30 mL of cow's milk-based formula and was observed for 4 hours. If clinical symptoms suggestive of an allergic reaction occurred (such as diarrhea, vomiting, skin rash, wheezing, etc.), the OFC was considered positive at the hospital; the child was managed according to the institutional protocol, and the home-based challenge was not continued.

- *Home-based phase:* Cases with no immediate reaction continued to increase the cow's milk dose at home, increasing by 30 mL every 2-3 days until reaching the target dose of 120-150 mL, appropriate for the child's diet. Before discharge, parents were provided with a home monitoring guide, clearly specifying symptoms to record and warning signs requiring immediate transport to the nearest emergency facility. During the home-based challenge, for non-emergency symptoms, parents recorded them in a diary and reported remotely (via Zalo/video call with images/videos if necessary); the physician assessed the report to decide whether to continue increasing the dose, maintain/reduce the dose, or stop the protocol and conclude a positive OFC when symptoms were consistent with CMA.

2.5. Definition and key variables

- *Positive OFC:* The child presents clinical symptoms consistent with CMA (primarily gastrointestinal and/or cutaneous manifestations) during the cow's milk challenge at the hospital or at home, assessed by the physician as being

related to the OFC, leading to a decision to stop or not further increase the dose.

- *Negative OFC:* The child completed the protocol to the target dose and completely replaced the previous therapeutic formula with regular cow's milk appropriate for their diet, without recording symptoms suggestive of CMA until the end of the follow-up period.

- *Indeterminate OFC:* Cases in which OFC protocol is not completed, the OFC protocol was not completed, follow-up was lost, or the challenge was discontinued for reasons unrelated to allergy (e.g., change in family decision, social reasons, lack of child cooperation, etc.), thus not classified as positive or negative and were excluded from the primary outcome analysis.

Reaction severity was classified into three levels: mild (localized, transient symptoms, not affecting general condition, no emergency intervention needed), moderate (clear symptoms requiring outpatient supportive treatment but no signs of dehydration, respiratory distress, hypotension, or anaphylactic shock), and severe/serious adverse events (requiring hospitalization, emergency management or adrenaline use).

Characteristics of the home-based OFC protocol implementation are described by whether the protocol was completed or not, conducted continuously according to the dose escalation schedule, or adjusted (step-back, temporary pause ≤ 48 hours, temporary pause > 48 hours). The number of OFC attempts until a conclusion was reached was calculated based on separate challenge episodes (considered separate when there was an interruption of ≥ 48 hours compared to the planned schedule). The number of OFC follow-up days was the number of days from the initial dose at the hospital to the date of OFC conclusion, including challenge episodes if interrupted.

2.6. Data processing

The data is processed using SPSS 20.0 software. Quantitative variables were presented as mean ± standard deviation or median (IQR), while qualitative variables were presented as frequencies and percentages. Comparisons between two groups were performed using appropriate statistical tests, with a significance level of $p < 0.05$.

2.7. Ethical considerations

The study was approved by the Ethics Committee in Biomedical Research of Children's Hospital 1 (Approval No. 164/GCN-BVND1). Parents were informed of the study objectives and procedures and provided written consent before the child's participation; all personal information was encoded and kept confidential.

III. RESULTS

3.1. General characteristics of the study population

From July 2024 to July 2025, a total of 51 children were included in the analysis, consisting of 29 children in the Suspected group and 22 children in the Tolerance group. The mean age of the total sample was 8.27 ± 4.48 months (Suspected group: 5.33 ± 2.02 months; Tolerance group: 12.1 ± 3.84 months); males accounted for 52.9%, and 64.7% of children resided in provinces outside Ho Chi Minh City. The majority of children had normal nutritional status (80.4%), while malnutrition accounted for 13.8%; personal history of allergy and family history of allergy were 2.0% and 13.7%, respectively. Initial clinical manifestations were predominantly gastrointestinal, with mucus and bloody stools accounting for 72.5%, eczema 19.6%, and wheezing 11.8%. Detailed characteristics are presented in Table 1.

3.2. Results of the oral food challenge

All 51 children underwent the OFC using the slow protocol with an initial dose of 30 mL at the hospital and gradual escalation at home. Overall results showed 40/51 children (78.4%) had a negative OFC and 11/51 (21.6%) had a positive OFC; the positive OFC rate in the Suspected group was 27.6% (8/29) and in the Tolerance group was 13.6% (3/22) (Table 2).

Among 11 positive OFC cases, recurrent symptoms were mainly in the digestive system (mucus stools, mucus and bloody stools, loose stools, vomiting) and skin (eczema); no acute

respiratory symptoms or anaphylactic shock were recorded. The time of symptom onset ranged from 2 to 19 days, with a mean of 8.64 ± 6.31 days after starting the cow's milk dose escalation; 45.5% of reactions occurred at a dose of ≤ 60 mL, 27.3% at 60- ≤ 90 mL, and 27.3% at > 90 mL. No positive cases occurred during the monitoring period at the hospital; all reactions were recorded during the home-based challenge phase. Detailed characteristics of the 11 positive OFC cases are presented in Table 3.

Regarding symptom concordance, 5/11 children (45.5%) had recurrent symptoms identical to the pre-elimination period, 5/11 (45.5%) had a partial recurrence accompanied by new symptoms, and 1/11 (9.1%) had completely different symptoms.

Table 1. Initial demographic and clinical characteristics (n=51)

Characteristics	Suspected group (n=29)	Tolerance group (n=22)	Total (n=51)
Demographics			
Age, months, mean ± SD	5.33 ± 2.02	12.1 ± 3.84	8.27 ± 4.48
Male, n (%)	17 (58.6)	10 (45.5)	27 (52.9)
Residing in HCMC, n (%)	10 (34.5)	8 (36.4)	18 (35.3)
Residing in other provinces, n (%)	19 (65.5)	14 (63.6)	33 (64.7)
Nutritional status and history			
Normal nutrition, n (%)	24 (82.8)	17 (77.3)	41 (80.4)
Mild malnutrition, n (%)	3 (10.3)	3 (13.6)	6 (11.8)
Severe malnutrition, n (%)	0 (0.0)	1 (4.5)	1 (2.0)
Personal history of allergy, n (%)	0 (0.0)	1 (4.5)	1 (2.0)
Family history of allergy, n (%)	5 (17.2)	2 (9.1)	7 (13.7)
Initial clinical symptoms			
Mucus and bloody stools, n (%)	22 (75.9)	15 (68.2)	37 (72.5)
Eczema, n (%)	6 (20.7)	4 (18.2)	10 (19.6)
Wheezing, n (%)	3 (10.3)	3 (13.6)	6 (11.8)
Mucus stools, n (%)	3 (10.3)	5 (22.7)	8 (15.7)
Loose stools, n (%)	3 (10.3)	1 (4.5)	4 (7.8)

3.3. Reactivity level and safety

Of the 11 OFC-positive children, 5 children (45.5%) experienced mild reactions and 6 children (54.5%) experienced moderate reactions. No cases of severe reactions or anaphylaxis were recorded at any stage. The follow-up period from initiation of OFC to conclusion (negative or positive) had a median of 28 days (20-30 day interquartile range, 3-66 day range), indicating that the majority of children completed OFC within approximately 3-4 weeks; The case lasting 66 days is due to multiple temporary interruptions caused by intercurrent acute illnesses, but the protocol was eventually completed. Some transient comorbidities such as upper/lower respiratory inflammation, skin redness or measles were noted during follow-up; two cases required hospitalization for treatment of these pathologies, but none of them had to stop OFC completely because of adverse events related to the challenge.

Table 2. OFC results (n=51)

OFC results	Suspected group (n=29)	Tolerance group (n=22)	Total (n=51)
Negative	21 (72.4%)	19 (86.4%)	40 (78.4%)
Positive	8 (27.6%)	3 (13.6%)	11 (21.6%)

Table 3. Characteristics of reactions in children with positive cow's milk OFC (n = 11)

Parameters	values
Number of positive OFC cases	11
Primary gastrointestinal symptoms, n (%)	Mucus stools: 4 (36.4); Mucus and bloody stools: 3 (27.3); Loose stools: 2 (18.2); Vomiting: 2 (18.2)
Cutaneous, respiratory and other symptoms, n (%)	Atopic dermatitis: 4 (36.4); Wheezing: 2 (18.2); Weight loss: 1 (9.1)
Time to symptom onset, days - mean ± SD (min-max)	8.64 ± 6.31 (2-19)
Reaction dose, n(%)	≤ 60 ml : 5 (45.5) 60 - ≤ 90 ml: 3 (27.3) > 90 mL: 3 (27.3)
Reaction severity, n(%)	Mild: 5 (45.5) Moderate: 6 (54.5) Severe: 0 (0)

3.4. Characteristics of implementing the home-based OFC protocol

The characteristics of implementing the home-based OFC protocol are presented in Table 2. In the total sample, 32/51 children (62.7%) performed the protocol continuously according to the dose escalation schedule and completed follow-up with a positive or negative conclusion; 19/51 children (37.3%) required protocol adjustments such as stepping down, temporary pause ≤ 48 hours, or > 48 hours and then restarting (Table 4). According to the number of OFC episodes, 42/51 children (82.4%) o required only one episode, 8 children (15.7%) required two episodes, and only one child (2.0%) required three episodes to reach a final conclusion.

Among the 9 children who required more than one OFC episode, the primary reasons were mild but inconclusive symptoms (5 cases) or intercurrent acute illnesses such as respiratory infections (3 cases); only 1 case was due to other family-related reasons. The rate of continuous protocol implementation according to the escalation schedule in the suspected group was 58.6% (17/29) and in the tolerance group was 68.2% (15/22).

Table 4. Characteristics of implementing the home-based cow's milk OFC (n = 51)

Protocol implementation characteristics	Suspected group (n=29)	Tolerance group (n=22)	Total (n=51)
Continuous protocol implementation	17 (58.6%)	15 (68.2%)	32 (62.7%)
Step-back / dose maintained without interruption	6 (20.7%)	2 (9.1%)	8 (15.7%)
Temporary pause ≤ 48 hours	0 (0.0%)	2 (9.1%)	2 (3.9%)
Pause > 48 hours, then restart	6 (20.7%)	3 (13.6%)	9 (17.6%)

IV. DISCUSSION

This study is one of the first reports in Vietnam to systematically evaluate the non-IgE-mediated cow's milk allergy challenge conducted mainly at home, under remote supervision by physicians. Among the 51 participating children, the majority were infants with relatively good nutritional status, presenting initially mainly with gastrointestinal symptoms, consistent with the mild-to-moderate non-IgE-mediated cow's milk allergy phenotype [1,6]. The positive OFC rate of 21.6% indicates that the majority of children were able to tolerate milk again after a period of appropriate elimination.

In the group of children suspected of CMA, the positive OFC rate was 27.6%. This rate is comparable to studies on infant cohorts with similar gastrointestinal symptoms; for instance, Aguirre et al. recorded 21% positive OFC in children with bloody stools suspected to be related to cow's milk, and Vasconcelos reported approximately 22% in children < 12 months with suspected gastrointestinal symptoms [13,14]. Thus, only about 1/4 - 1/3 of those with suspicious clinical manifestations were truly still allergic; the remainder were likely suffering from transient and self-limiting functional gastrointestinal disorders. This aligns with recent recommendations, wherein the diagnosis of non-IgE-mediated CMA always involves two mandatory phases: short-term cow's milk elimination and controlled reintroduction via OFC to confirm the diagnosis, avoiding unnecessary prolonged elimination diets [1,4-6,10,12] . Some authors even suggest a "watch and wait" strategy in healthy infants with only mild gastrointestinal symptoms and normal growth, proceeding with short-term elimination and subsequent OFC only if symptoms persist; this approach helps reduce the risk of misattributing functional gastrointestinal disorders to cow's milk and limits the unnecessary use of therapeutic formulas [11,15,16].

In the tolerance assessment group after an elimination period, the positive OFC rate was only 13.6%, meaning nearly 9 out of 10 children were able to tolerate milk again, consistent with the favorable natural history of non-IgE-mediated cow's milk allergy [1,6]. A study by Meyer et al. in the UK following 130 children with non-IgE-mediated CMA showed that 46% fully tolerated milk after an average of 17 months of elimination, and an additional 31% achieved partial tolerance using a ladder reintroduction method [17]. The fact that over 80% of children in the current study tolerated cow's milk after an appropriate elimination period demonstrates the positive role of monitoring and controlled re-challenge in tolerance recovery. This result also confirms that, for non-IgE-mediated types, maintaining an elimination diet for an excessively long period is unnecessary if the child has a good clinical response and is reassessed at the right time [1,10,11].

Among the 11 children with positive OFC, recurrent symptoms were mainly gastrointestinal and cutaneous, with no cases of acute dyspnea or anaphylactic shock, consistent with the delayed non-IgE mechanism and the high-risk exclusion criteria (positive skin prick test, history of early urticaria/anaphylaxis, FPIES) [4,5]. Previous reports have also noted the possibility of some non-IgE cases shifting to an IgE-mediated phenotype over time, so patients with symptoms suggestive of an IgE mechanism are not suitable for home challenge protocols and need to be evaluated and monitored closely in a hospital setting [1,6].

The time to symptom onset ranged from 2 to 19 days, averaging about 9 days after starting the cow's milk dose increase; nearly half of the reactions occurred at a dose of ≤ 60 mL. This characteristic explains why OFC in non-IgE CMA cannot be shortened to a single session at the hospital but requires a prolonged slow dose-escalation protocol at home, accompanied by strict monitoring instructions. In terms of counseling, determining the reaction threshold dose helps warn families about the risk of symptom recurrence if the child is accidentally exposed to small amounts of cow's milk, while suggesting that children reacting only at higher thresholds may be suitable candidates for ladder-based reintroduction strategies to promote tolerance [6,7,12,17].

Regarding safety, no severe reactions or anaphylactic shock occurred throughout the study; all positive reactions were mild to moderate and managed as outpatients. This result is consistent with international reports on home milk reintroduction or the milk ladder in children with non-IgE gastrointestinal allergy once FPIES and risk factors for severe reactions have been excluded [12,17]. With a selection strategy including only children with mild-to-moderate manifestations, negative skin prick tests, no uncontrolled asthma, and no history of anaphylaxis, the data suggest that home-based slow OFC can be safely implemented in low-risk pediatric groups if adequately prepared and monitored [4,6,12,17].

The time from OFC initiation to conclusion had a median of 28 days (IQR 20-30), meaning the majority of children could complete the protocol and determine tolerance status within 3-4 weeks. The case extending to 66 days was primarily due to the current protocol requiring temporary OFC suspension when the child had an acute illness to ensure safety and avoid confounding; the child still completed the protocol without events, suggesting the process can be operated flexibly and temporary suspension criteria can be considered for adjustment depending on the specific clinical context.

The feasibility of home-based OFC was demonstrated by the fact that 62.7% of children completed the protocol continuously according to the dose-escalation schedule, and 82.4% required only a single OFC episode to reach a conclusion. Cases requiring step-back or repetition were mainly due to mild, inconclusive symptoms or intercurrent acute illnesses rather than severe adverse events. These results are consistent with reports on home-based milk reintroduction or milk ladder approaches in children with non-IgE-mediated CMA, in which severe events are rare once high-risk patients have been excluded. They also indicate that a home-based OFC model supported by detailed instruction sheets and remote communication channels is feasible in real-world settings [6,10,12,17].

From a practical perspective, the study results suggest that in children with mild-to-moderate non-IgE-mediated cow's milk allergy who have been screened to exclude IgE mechanisms and FPIES, OFC can be organized primarily at home following a slow protocol, under remote supervision by physicians. The selection of an appropriate model (fully home-based or two-phase hospital-home) needs to be individualized according to clinical characteristics, the family's anxiety level and ability to cooperate, the treatment team's experience, and the accessibility of local emergency care [4,6,10]. The study still has some limitations such as a small sample size, few positive cases and lack of long-term follow-up; larger studies with comparison groups and longer follow-up durations will help further affirm the role of home-based OFC and optimize the process for this patient group in the context of Vietnam.

V. CONCLUSION

In a population of 51 children suspected of or diagnosed with mild-to-moderate non-IgE-mediated CMA, the slow-protocol oral food challenge conducted primarily at home proved to be safe and feasible, with 78.4% of children tolerating cow's milk again and no severe reactions recorded. All positive reactions appeared late during the home dose escalation phase, mainly consisting of mild-to-moderate gastrointestinal and skin symptoms, consistent with non-IgE mechanisms. These results suggest that, when selecting the correct low-risk subjects and having appropriate guidance and supervision, home-based OFC can be a practical and effective strategy to confirm diagnosis, limit unnecessary prolonged elimination diets, and facilitate early restoration of a milk-containing diet for the majority of children.

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