The Flemish milk ladder: a tool for home-based cow's milk reintroduction in children with non-IgE-mediated cow's milk allergy

Liselot De Vlieger [a], Tessa Bosmans [b], Marianne Diels [b], Lisa Nuyttens [a,b], Marc Raes [b,c], Jasmine Leus [b,d], Sophie Verelst [b,c], Dominique MA Bullens [a,b], Katrien Coppens [b,e]

[a] KU Leuven, Department of Microbiology and Immunology, Research group of Allergy and Clinical Immunology, Leuven, Belgium
[b] Clinical Division of Pediatrics, UZ Leuven, Leuven, Belgium
[c] Clinical Division of Pediatrics, Jessa Hospital, Hasselt, Belgium
[d] Clinical Division of Pediatrics, AZ Maria Middelares, Ghent, Belgium
[e] Clinical Division of Pediatrics, Imelda Hospital, Bonheiden, Belgium

Liselot.devlieger@kuleuven.be

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Abstract

Cow's milk allergy is one of the most prevalent food allergies in young children affecting 2 to 5 % of the infants in developed countries. The classic treatment of this food allergy consists of a strict avoidance diet. However, literature states that 70% of cow's milk allergic children can tolerate extensively heated (baked) milk products and that incorporating baked milk products into the diet accelerates tolerance towards unheated milk. In this paper, we focus on the gradually reintroduction of cow's milk using a Flemish milk ladder for children with non-IgE mediated cow's milk allergy. Hereby, we examined the utility and user-friendliness of this tool to guide both clinicians and parents through the reintroduction of cow's milk, since there is still a wide variety in clinical practice on how and when to introduce cow's milk in these children. The Flemish milk ladder was evaluated through surveys, open interviews and expert panels composed of academics, clinicians and dieticians. In total we received 22 surveys from regional pediatricians and parents, in which the overall feedback on the utility and user-friendliness of the milk ladder was positive. The suggestions that we received of the experts in the field and parents regarding this milk ladder were incorporated into a new version, which included a reduction of the number of steps, availability of more recipes and healthier options within each step. In conclusion, we present a helpful and safe guide to gradually reintroduce cow's milk-containing products at home in children with non-IgE mediated cow's milk allergy, considering the eating habits of the Belgian population.

Introduction

Cow's milk allergy (CMA) is one of the most common food allergies in early childhood with an overall prevalence of 2 to 5% (1). This food allergy is defined by a hypersensitivity reaction to one or more cow's milk proteins (CMP), which are in most cases β-lactoglobulin or caseins (1). The immunological response of CMA can be IgE-mediated or non-IgE mediated or in some presentations a combination of both (2). As a result, this food allergy is characterized by a wide spectrum of clinical presentations ranging from mild, moderate to severe (1,2). In case of IgE-mediated CMA, symptoms can rapidly evolve within minutes to several hours after ingestion of cow's milk-containing products and may even result in a potentially life-threatening anaphylaxis (1,2). Hereby, IgE-mediated reactions are mainly manifested at the level of the skin, gut and/or respiratory tract (1,2). Non-IgE mediated CMA encompasses a wider range of disorders mostly affecting the gastro-intestinal system (protein-induced allergic proctocolitis (FPIAP), protein-induced enterocolitis (FPIES), gastrointestinal dysmotility & cow's milk protein-sensitive enteropathy (FPE)), skin (eczema) or in very rare cases the lungs (Heiner syndrome) (1,2). Symptoms may vary from mild to moderate (e.g. reflux, colic, diarrhea, constipation, blood in stool) to severe forms of non-IgE mediated CMA (e.g. severe eczema, failure to thrive, anaemia, hypovolemic shock) (1,2). An overview of the different manifestations of CMA are given in Table 1.

Table 1 : *Table 1: Overview of the different manifestations of cow's milk allergy (1,2)*

IgE-mediated CMA	Non-IgE mediated CMA	Mixed mechanism
Urticaria and angio-edema	Allergic dysmotility: reflux, diarrhea, constipation, colic's	Atopic dermatitis
Gastro-intestinal symptoms: vomiting, abdominal pain, diarrhea	FPIAP: well infant with bloody stools	Eosinophilic esophagitis: abdominal pain, dysphagia, reflux with eosinophilic infiltration in the esophagus
Airway symptoms: stridor, cough, wheeze	FPIES: severe vomiting, pallor, hypotension	
Shock, anaphylaxis	FPE: chronic diarrhea, vomiting, failure to thrive	
	Heiner syndrome: recurrent pneumonia	

CMA: cow's milk allergy, FPIAP: protein-induced allergic proctocolitis, FPIES: protein-induced enterocolitis, FPE: cow's milk protein-sensitive enteropathy

The prognosis of CMA is usually favourable, with the majority of children being able to tolerate cow's milk by the age of 5 (2). Hereby, tolerance will develop faster in case of non-IgE mediated CMA, while IgE-mediated responses are known to be more persistent (2). Risk factors for a delayed or persistent form of CMA are severe symptoms on initial presentation, presence or persistence of high specific IgE's to cow's milk (> 20 kU/l), multiple food allergies and the presence of respiratory allergies (3). In case of IgE-mediated CMA, tolerance development can be monitored by use of skin prick tests and measurement of cow's milk specific IgE levels (3–5). When tolerance is suspected, an oral food challenge with cow's milk (baked milk e.g. boiled for 20 minutes or unheated fresh milk) can take place in a controlled hospital environment (3–5). Unfortunately, there are no reliable tests available to predict tolerance in non-IgE mediated CMA (3–5). Moreover, the timing of tolerance development seems to be variable and dependent on the clinical picture (Table 2) (3–5). Infants with mild gastro-intestinal symptoms, atopic dermatitis or FPIAP seem to develop tolerance by their first birthday whereas children with FPIES and FPE only develop tolerance by the age of 2 to 3 years (4,5).

Table 2 : *The timing of tolerance development in function of the clinical presentation of cow's milk allergy (3–5)*

Manifestations of CMA	Age of tolerance development
GI-dysmotility	Mostly resolved by the age of 6-12 months
FPIAP	Mostly resolved by the age of 9-12 months to 3 years
Atopic dermatitis	Sensitivity to cow's milk mostly resolved by the age of 12-24 months
FPIES	Mostly resolved by the age of 2 years
FPE	Mostly resolved by the age of 2-3 years
Eosinophilic esophagitis	Unsure, possibly no tolerance development

GI: gastro-intestinal, CMA: cow's milk allergy, FPIAP: protein-induced allergic proctocolitis, FPIES: protein-induced enterocolitis, FPE: cow's milk protein-sensitive enteropathy
Note: Adapted from Nowak-Wegrzyn A, Katz Y, Mehr SS, Koletzko S. Non-IgE-mediated gastrointestinal food allergy. J Allergy Clin Immunol. 2015 May;135(5):1114-24. doi: 10.1016/j.jaci.2015.03.025. PMID: 25956013.

The classic treatment of CMA consists of a strict elimination diet. However, recent studies have shown that 75% of CMA children are able to tolerate extensively heated (baked) milk products (e.g. cookie/biscuit, muffin…) and that incorporating baked milk into the diet accelerates tolerance towards unheated milk (6). In 2013, a British expert panel developed a milk ladder as a tool to gradually reintroduce milk-containing foods, from lowest to highest allergenicity, for children with non-IgE mediated CMA (7). This is based on the evidence that thermal processing of CMP and the interaction with carbohydrates and fats reduces the allergenicity (8). To date, no evidence suggests that the British milk ladder could accelerate tolerance induction. However, it has proven to be a useful tool for healthcare professionals as it provides a uniform practical guidance for the reintroduction of cow's milk (9). It should be noted that the British milk ladder still requires country-specific adjustments (9). In this article we present a Flemish version of this milk ladder and evaluate the utility and user-friendliness of this tool by means of surveys, open interviews and expert panels.

Materials and method

Development of the Flemish milk ladder

Considering that the British milk ladder contained some traditional British dishes (e.g. Shepherd's Pie) a group of dieticians and doctors from the Department of Paediatric Allergy and Gastroenterology of UZ Leuven collaborated with Mead Johnson to develop a Flemish version of this milk ladder. The main modifications included: replacing the regional products of England, substituting the high-sugar and fat foods with healthier alternatives and combining a number of steps. Originally, the Flemish milk ladder was developed for two age groups, children aged 1-1.5 years (Figure 1a) and 1.5 years and older (Figure 1b). In the youngest children cow's milk was reintroduced through 15 steps, while in older children the milk ladder contained 17 steps. It was recommended that each step should take a minimum of 3 days in agreement with the physician and/or dietician.

The use of the Flemish milk ladder in clinical practice

The goal of the Flemish milk ladder entails the home reintroduction of cow's milk in children with mild to moderate non-IgE-mediated CMA. An observational study (S59587) was started in 2017 to evaluate the user-friendliness of the Flemish milk ladder in clinical practice. Specifically, our aim was to determine whether parents and pediatricians would find this an easy and helpful tool to guide them through the reintroduction of milk-containing foods. This study was approved by the Ethics Committee Research of UZ/KU Leuven (study nr. S59587).

The goal of this observational study was to evaluate the Flemish milk ladder by means of 50 anonymized questionnaires to the physician and parents. Hereby, each questionnaire was filled out on the experience of a single child. The inclusion criteria included the following: age 1 year and older, a clinically established non-IgE mediated CMA and the absence of positive IgE's and/or positive skin prick test to cow's milk. The survey for the parents included questions on: the demographics of the child, the different steps (duration, arising difficulties, allergic reactions…), findability of the products on the Flemish market and tolerance after completing the milk ladder (final step reached, total duration…). In addition, parents were free to give additional remarks on the Flemish milk ladder. The survey for the physicians consisted of clinical data on: demographics, initial reaction towards cow's milk (age, presentation, preferred diagnosis…), results of allergy tests (skin prick test and sIgE levels), cow's milk provocation test, nutrition history (breastfeeding, infant formula...), multiple food allergies, their recommended duration of each step and the indication for which they opted to use the milk ladder. After completing the milk ladder, physicians filled out additional information on: the different steps (duration, clinical manifestations…), the use of rescue medication, final step reached (total duration, reason of stopping earlier, was the stop rightfully…), satisfaction score and adjustments that they would recommend.

The Flemish milk ladder was presented and distributed along with the questionnaires during the local quality evaluation group (LOK/GLEM) meetings of the pediatricians in Flanders. Representatives of Mead Johnson were partially responsible for the distribution and collection of the closed envelopes with anonymous questionnaires from the regional pediatricians. An additional assessment was accomplished by using the thinking aloud test and expert panel groups (10). In the thinking aloud method, an open interview (not recorded) was conducted to assess the opinion of various experts in the field of allergy (10). Concerning the expert panel groups, these were composed of academics, clinicians and dieticians involved in the treatment and/or research of food allergy. The first expert panel was part of the Pediatric Allergy and Asthma Meeting in 2017 in London where several experts from Flanders and Netherlands attended. A second expert panel took place in Leuven in 2017 with the help of the postgraduate course 'Allergy and Clinical Immunology' organized by UZ Leuven. A final expert panel was held in 2021 in Leuven, with the original group of experts that developed the Flemish milk ladder, to incorporate the received feedback into a new version.

Results

Surveys

A total of 150 surveys were distributed among 30 pediatricians. However, only 22 envelops with anonymized surveys from the pediatrician and parents were returned to us, of which 16 for the young child and 6 for the older child. The ultimate goal of 50 questionnaires was not achieved. Most of the pediatricians reported not having enough time to process them or did not receive the surveys back from the parents.

The pediatricians used the Flemish milk ladder to reintroduce milk in children with mild to moderate non-IgE mediated CMA presented as FPIAP, gastrointestinal dysmotility or FPE. The majority of these children were exclusively breastfed for 2 to 6 months and switched to a hypoallergenic infant formula afterwards. Only a small number of mothers followed an elimination diet over a longer period of time and kept breastfeeding after 6 months. The main symptoms at initial presentation included gastro-intestinal complaints (e.g. cramps, anal blood loss, diarrhea, constipation, vomiting…) in combination with reflux, eczema, restless behavior and/or suboptimal weight. Four children already tolerated baked milk while 18 children reintroduced milk into their diet for the first time on introduction of the milk ladder. The cow's milk sIgE levels were measured in 15 of the 22 children of which all were below the cut-off value of 0.10 kU/L. The skin prick test was performed in 13 children, of which three had a positive result. However, these three children had cow's milk sIgE's below the 0.10 kU/L. In total, most of these children had concomitant hen's egg, soy, peanut and/or treenuts allergy while only eight were exclusively diagnosed with CMA.

Eighteen of the 22 children spent 2 to 4 days on each step of the Flemish milk ladder, which was in line with the advice of their pediatrician or dietician. However, four children needed 7 to 14 days to complete each individual step. In three children this prolonged time duration was attributed to a previously failed reintroduction, picky eating behavior or practical issues for the parents

Figure 1 : *Flemish milk ladder for children aged 1-1.5 years (a) and 1.5 years and older (b)*

during the week. The fourth child prolonged step 1 from 3 to 7 days by advice of their pediatrician due to symptoms (eczema, cramps and diarrhea) when reintroducing baked milk in step 1. Ultimately, seventeen children developed complete cow's milk tolerance and reached the final step of the milk ladder. During the reintroduction of cow's milk, only four of these 17 children experienced symptoms (diarrhea, eczema). In general, most of the symptoms occurred during the last steps of the milk ladder for both age categories. In addition, seven children replaced or skipped a step of the milk ladder since they disliked a product, ate larger quantities of a product from the start or replaced cow's milk by growth milk or follow-up formula. Five of the 22 children had to stop the reintroduction of cow's milk by advice of their pediatrician due to diarrhea, cramps and/or eczema. The majority of these children were between 1 and 1.5 years of age and experienced more severe symptoms (e.g. diarrhea, vomiting, anal blood loss, suboptimal weight) at the initial time of diagnosis. In addition, two of these five children reached partial tolerance for fermented milk (e.g yoghurt), while the other children were put on an elimination diet again.

The overall feedback from the regional pediatricians on the Flemish milk ladder was positive, with an average satisfaction score of 75%. Recommendations and comments made by the clinicians included reducing the number of steps, eliminating the sugar-rich products (e.g. baby cereals, pancakes), lowering the portions for the smallest children and eliminating the step with pasteurized milk since several parents indicated that they weren't familiar with this product. In addition, parents mentioned the need of alternative products for children with concomitant hen's egg allergy and/or gluten intolerance.

Thinking aloud method

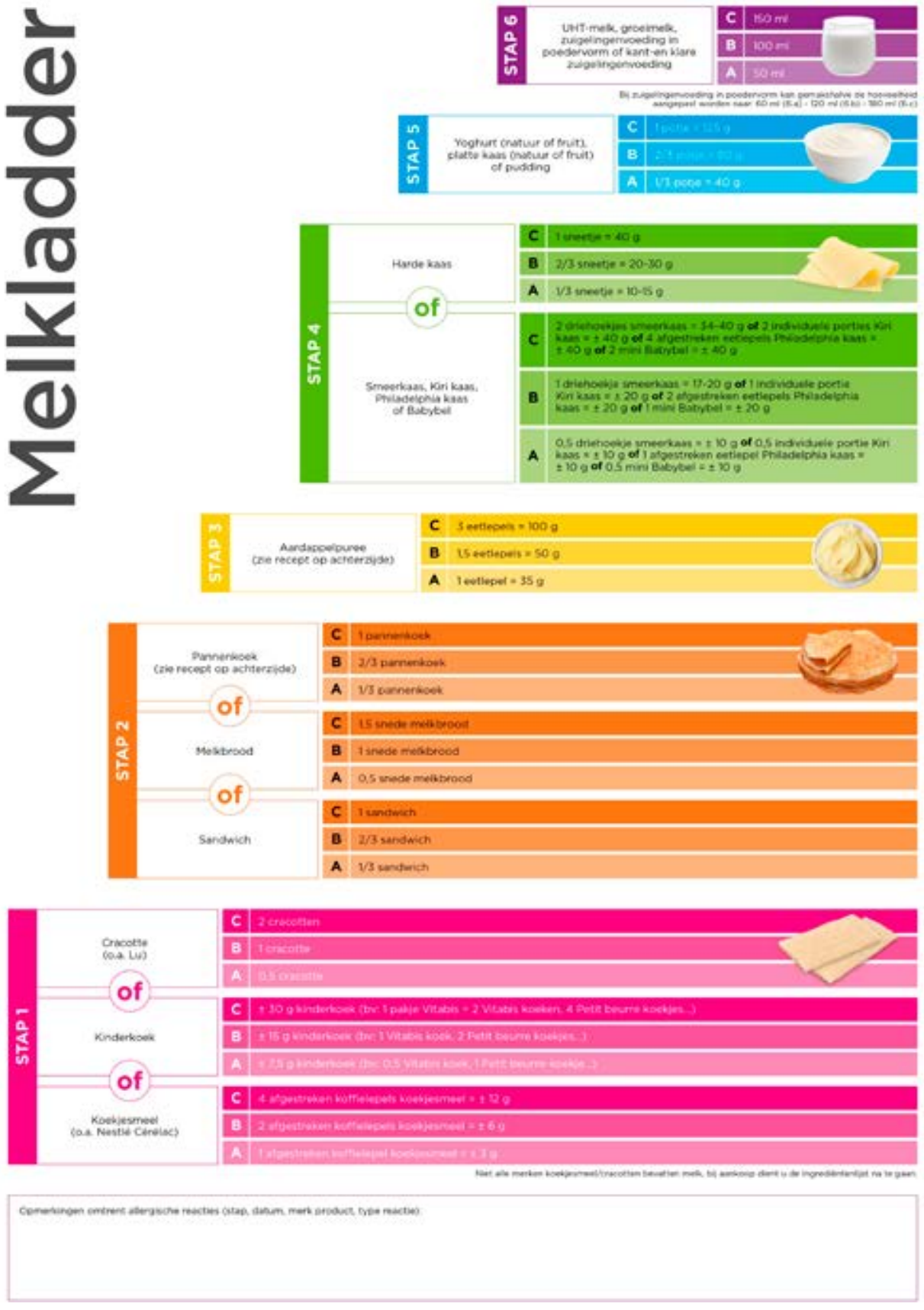
Both clinicians and dieticians reported that the Flemish milk ladder was a valuable and user-friendly tool for the reintroduction of milk. This applies for children with non-IgE-mediated CMA who already tolerated baked milk and those who reintroduced milk into their diet for the first time on introduction of the ladder. There were no negative remarks on the number of steps the milk ladder contains. Parents even mentioned to their physician that they felt more comfortable since the stepwise induction was spread over a longer period of time. The children who had a mild allergic reaction during the reintroduction of milk, usually had this during the last steps of the milk ladder. In these circumstances, the child temporarily returned to a previous step or the time period of 3 days was extended by advice of their treating physician. The most recurring remarks were that parents weren't familiar with pasteurized milk, the high-sugar content of some products, not listing growth milk or follow-up formula and the lack of alternative products for children with multiple food allergies or when children don't like a product.

Expert panels

In the first expert panel, Belgian and Dutch pediatricians, allergists and dieticians focused on comparing the Flemish and Dutch version of the milk ladder. The Dutch milk ladder was an initiative from the dietician's alliance in food hypersensitivity (DAVO) and similar to the Flemish milk ladder based on the Milk Allergy in Primary (MAP) Care guidelines published in 2013. The tolerance induction takes place through 12 steps, with the advice to contact a dietician after completing step 4, 7 and 10. Each step requires 1 week of reintroduction, and when children can finally tolerate small amounts of unprocessed sterilized milk or follow-up formula the Dutch milk ladder refers to the recommended number of dairy products for each age category. However, this milk ladder again contains a number of regional brands (e.g. knappertjes van Verkade, sprinkles of Venz) that are less known in Belgium which highlights the need for different versions of the milk ladder customized to the eating habits of each region. In general, the experts advised to reduce the number of steps in the Flemish milk ladder starting with the deletion of pasteurized milk. Furthermore, they indicated that it would be interesting to incorporate the advised number of dairy products and highlight the role of the dietician, as was done in the Dutch milk ladder.

In the last two expert panels, Belgian pediatricians, allergists and dieticians tried to incorporate the feedback that we received into a new version of the Flemish milk ladder (Figure 2). Hereby, we created an official leaflet with explanatory notes, which is going to be distributed by Mead Johnson. In this newest version, the two milk ladders for different age categories are combined into one and the number of steps reduced to six. It should be noted that within each step of this new milk ladder the corresponding milk-

Figure 2 : *New version of the Flemish milk ladder for children aged 1 year and older*



containing products are still introduced gradually. Furthermore, similar to the first version each step (e.g. 1a, 1b & 1c) requires 3 days of reintroduction. As in the Dutch milk ladder, we have provided different options of milk-containing foods within each step, giving families a broader range of foods to choose from including some healthier options. In addition, the parents are provided with recipes for some of the products (Figure 3). For practicality reasons, the quantities of the foods are also provided in the form of spoons. In the last step of the milk ladder, we have added the reintroduction of growth milk and infant formula on top of sterilized milk (UHT – 140 to 150°C for 2 seconds). After successfully completing all six steps children can eat all milk-containing products safely except for pasteurized milk which is not part of the newest version of the Flemish milk ladder. Parents need to consult their physician or dietician before reintroducing this product, since pasteurized milk is only heated for 15 seconds at 72 degrees. Additional alternative products for children with multiple food allergies are going to be provided in a supporting website. Finally, in the newest version we place more emphasis on the fact that the milk ladder is intended for the treatment of children with non-IgE mediated CMA and not for IgE-mediated CMA.

Discussion

In general, we received positive feedback on the user-friendliness and safety of the Flemish milk ladder as a tool to reintroduce milk at home in children with non-IgE mediated CMA. Hereby, the suggestions of experts and parents were incorporated into a new version of the Flemish milk ladder which includes a reduction of the number of steps, availability of more recipes, healthier options within each step and the removal of pasteurized milk. However, it should be noted that the milk ladder is not an evidence-based tool, but rather a tool based on the opinion of experts and the knowledge that by heating CMP and the interaction with carbohydrates and fat the allergenicity of CMP reduces (8). Nevertheless, the Flemish milk ladder seems to be a useful and safe guide to help both clinicians and parents through the gradual reintroduction of cow's milk by means of surveys, interviews and expert panels. This applies for children who already tolerated baked milk as well as those who introduced cow's milk into their diet for the first time. However, one drawback of our observational study was that we only received 22 surveys instead of the intended 50. On the other hand, we were able to obtain feedback from a considerable number of clinicians, dietitians and researchers who used the Flemish milk ladder in clinical practice by interviews and expert panels.

Although full cow's milk tolerance is not always achieved when using the milk ladder, it is possible that children can reach partial tolerance for baked milk or fermented milk products while still reacting to raw milk. Consequently, the Flemish milk ladder is also helpful to broaden the diet of children with non-IgE mediated CMA without reaching full milk tolerance. By doing so, children can avoid unnecessary restrictions of baked milk or fermented milk-containing foods, which may improve the nutrition as well as the quality of life of both children and parents. It is recommended that each step takes at least three days, as symptoms can occur up to 72 hours after ingestion. In case a child experiences symptoms during the reintroduction, we advise to return to a previous step in the milk ladder or stop the introduction of cow's milk completely. Depending on the age of the child a new attempt of cow's milk reintroduction can be made after a period of 3 to 6 months. In general, guidance by a dietician is recommended when using the milk ladder, this to provide safe alternatives, avoid deficiencies when following a cow's milk-free diet and to explain the use of the milk ladder especially in case of multiple food allergies.

To date, no severe allergic reactions have been reported during the home-reintroduction of milk by use of the Flemish milk ladder. However, we should emphasize that this tool can only be used in children with mild to moderate non-IgE mediated CMA presented as FPIAP, gastrointestinal dysmotility or FPE. Hereby, caution is advised when using this tool for more severe presentations of non-IgE-mediated CMA, with the possibility of an acute allergic reaction at home. This can be the case for acute FPIES, where the child is at risk of experiencing delayed repetitive vomiting and diarrhea usually within 1 to 4 hours after ingestion of the offending food which can ultimately lead to a hypovolemic shock (11). On the other hand, children with chronic FPIES who present with chronic diarrhea, vomiting and failure to thrive due to a chronic exposure to the food trigger can also react with acute symptoms upon reintroduction of cow's milk after following a cow's milk-free diet (12). In addition, 25% of children with FPIES may develop IgE antibodies of which some can evolve to an acute food allergy (13). It is therefore recommended to assess allergic sensitization to cow's milk in these children by either performing a skin prick test or measuring the specific IgE levels. In case of severe symptoms, the presence of IgE antibodies or a positive skin prick test to cow's milk, a hospital-based provocation of baked cow's milk is usually warranted and the use of the milk ladder contraindicated. This is also the case for mixed forms of CMA, such as eosinophilic esophagitis, where the child has to follow a cow's milk elimination diet over a longer period of time and reintroduction is only considered after consulting a pediatric gastroenterologist.

Finally, although 75% of the children with IgE-mediated CMA can become tolerant towards baked cow's milk, the general advice is to perform the baked milk challenge in the hospital due to the risk of severe symptoms (6). In contrast to non-IgE mediated CMA, where the introduction can take place at home by use of the milk ladder as there is no risk of an anaphylactic shock. This was recently supported by a worldwide survey of healthcare professionals, where the majority of the clinicians considered the home setting as unsafe for the performance of a baked milk challenge or use of the milk ladder in IgE-mediated CMA (9). In the management of IgE-mediated CMA, the physicians are therefore advised to frequently evaluate the cow's milk sIgE levels and skin prick test. Based on the results of these allergy tests and the severity of the initial symptoms, the physician can decide whether to perform an in-hospital oral food challenge to test for acquired baked milk tolerance. Hereby, the recent study of De Boer et al. showed that cow's milk sIgE levels were a better predictor for baked milk tolerance in comparison to the skin prick test (14).

Conclusion

The Flemish milk ladder is an adapted tool that physicians and dieticians can use to gradually reintroduce cow's milk at home in children with mild to moderate non-IgE-mediated CMA. This reintroduction takes place through six steps, of which each step requires a minimum of 3 days. Although it is not an evidence-based tool parents, clinicians and dieticians consider it to be a helpful guide to reintroduce cow's milk-containing products.

Conflicts of Interest

DMAB received consulting fees from Mead Johnson. KC and MR participated in webinars organized by Mead Johnson. LDV, TB, MD, LN, JL and SV declare to have no conflict of interest.

Figure 3 : *Accompanying recipes for the new version of the Flemish milk ladder*

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