

Standardization of food allergen ladders for optimal effectiveness and patient safety

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ABSTRACT

The use of extensively heated (EH) milk and egg products, and dietary advancement therapies such as milk and egg ladders is increasingly common for the management of milk and egg allergies. Although the majority of patients with milk and egg allergies will outgrow their allergies, the ability to tolerate extensively hydrolyzed forms of these allergens is an early indicator of developing long-term tolerance. The denaturation of conformational epitopes during the heating process reduces the allergenicity of these proteins, which makes patients who are EH tolerant more likely to tolerate progressively more of these proteins.

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This article highlights the ongoing use of milk and egg ladders for non-immunoglobulin E (IgE) mediated and IgE-mediated allergies, as suggested by various guidelines and studies. The debate surrounding the influence of ladders on allergy resolution is discussed, with limited evidence supporting the acceleration of resolution through extensively heated (EH) milk or egg ingestion. However, the long-term success and safety of these approaches require further evaluation, as evidenced by the potential for mild, moderate, and severe reactions.

Patient selection is crucial for ladder success, and factors associated with favorable outcomes are highlighted. Importantly, clinicians should be cautious not to translate the success with the patients predominantly low risk to the less-common high-risk phenotypes. Protocol standardization is essential for evaluating the long-term success of milk and egg dietary advancement therapies (DAT), given the variability in allergenic protein doses due to differences in preparation methods and food types. Patient preparation and counseling are fundamental for safe

implementation, emphasizing the need for adequate education about risks, procedures, risk-mitigation strategies, and comorbidity control.

Future research should focus on determining the optimal age for ladder implementation, quantifying allergenic protein amounts in ladder progression, and improving communication strategies for caregivers and health-care providers.

Although milk and egg allergies remain some of the most common food allergies among infants and young children, the majority of patients with milk and egg allergies will outgrow their allergies.^{1,2} One of the earliest indicators of developing long-term tolerance is the ability to ingest egg or milk in the baked or EH form.³ Early studies of the tolerance of EH protein suggest that ~75% of those with egg or milk allergies could tolerate baked forms of these allergens.^{3,4} This degree of tolerance is hypothesized to be related to the presence of conformational epitopes within these allergenic proteins.⁴ During the heating process, these conformational epitopes are denatured, which reduces the allergenicity of these proteins. These epitopes may also be sensitive to pH, enzymic degradation, or fermentation. In general, children with transient egg or milk allergy may tolerate EH proteins because they generate IgE against these conformational epitopes. As a patient begins to outgrow his or her allergy, he or she may be able to tolerate progressively more of this protein, and/or protein that is less extensively altered to reduce allergenicity. As such, the implementation of milk and egg ladders was reported to be a feasible option for these patients who are EH tolerant.⁵ These DATs represent a spectrum of approaches from classic oral immunotherapy (OIT) to ladders and simple EH-protein ingestion.⁶

Initially, the milk ladder was suggested in the Milk Allergy in Primary Care (MAP) and subsequent International Milk Allergy in Primary Care (iMAP) guidelines to expand the diets of patients with non-

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IgE-mediated milk allergy.^{5,7} The ladder consists of escalation of ingestion of foods in which the protein is progressively less denatured, *e.g.*, baked muffin, pancake, cheese, yogurt, milk. However, in 2014, the British Society of Allergy and Clinical Immunology suggested that a milk ladder approach may also be suitable for IgE-mediated cow's milk allergy.⁸ A 2017 survey of health-care practitioners reported that 70% of clinicians were using milk ladders for patients with non-IgE-mediated allergies, whereas 60% used a ladder for IgE-mediated allergies at home and/or in a hospital setting.⁹ Although ladders were initially reported for milk, in 2021, British Society of Allergy and Clinical Immunology published an egg ladder guideline.¹⁰ Since then, other countries and groups have reported their success with these ladder approaches, including a report of the implementation of milk ladders in infants with safe and effective results.^{11,12}

However, the long-term success of these approaches has yet to be well studied. One report of 187 patients, with a mean age of 6.8 years, who were tolerant of baked milk (BM) demonstrated that 43% had progressed to direct milk, 20% ingested less cooked (than the original baked product), 10% continued only to ingest BM, and 28% strictly avoided all forms of milk.¹³ Eleven patients reported severe reactions, and 3.2% of patients with eosinophilic esophagitis were reported. Ongoing follow-up should critically evaluate the actual safety and effectiveness of these DAT approaches.

DOES INGESTION OF EH MILK AND EGG PRODUCTS OR LADDERS HASTEN THE RESOLUTION OF EGG OR MILK ALLERGY?

An ongoing debate centers around whether ladders influence egg or milk allergy resolution.¹⁴ A 2017 systematic review found only weak evidence, with no clear indication that implementation of EH milk or egg accelerates resolution.¹⁵ The only randomized, double-blind, placebo controlled study of baked egg (BE) ingestion did not demonstrate hastened tolerance.¹⁶ Forty-three children who were BE tolerant, unheated egg allergic, with an average age of 2 years, consumed 1.3 g of BE protein two to three times a week for 6 months. To avoid the possibility of desensitization, the patients discontinued the ingestion before exit oral food challenge (OFC) to raw egg. There was no difference in raw egg tolerance between the intervention and control groups (23.5% versus 33.3%, respectively; not significant). However, the brief intervention period and practicality of raw egg ingestion were limitations of this study because most patients do not routinely consume raw egg.¹⁶ Most importantly, this report evaluated a group of patients already tolerant of BEs, a

phenotype that may already be in the process of developing tolerance.

The resolving and persisting allergic phenotypes remain a fundamental distinction point and may be predetermined. The presence of filaggrin loss-of-function mutations seems to be associated with egg and milk allergy persistence.¹⁷ Implementation of BE and/or BM ingestion in these persistent phenotypes has yet to be extensively studied and seems to be riskier than in the resolving phenotype. Extrapolating the success of ladders with patients at low risk to the high-risk phenotypes has led to poor outcomes. As such, the standardization of approaches for patient selection, procedures, and even education should be considered for DATs.

PATIENT SELECTION IS KEY TO EGG AND MILK LADDER SUCCESS

Most studies that evaluated milk and egg ladders have been among low-risk, resolving phenotypes. Ball and Luyt¹⁸ published an evaluation of 86 children allergic to milk and with a median skin-prick test (SPT) size of 4 mm. Sixty-five reactions were reported, all mild to moderate, including rash, hives, angioedema, and vomiting. No epinephrine was reported. Of note, ongoing support was provided by a dietitian. Similarly, an Australian report implemented a six-stage egg ladder in children with egg allergy and with a mean SPT result of 3.1 mm and a mean age of 40 months.¹⁹ Of the patients, 87.2% introduced BEs initially at home. Most reactions were mild, with one dose of epinephrine used, although 21.4% of the patients were reported to have experienced a moderate-to-severe reaction. Only 42.6% reported completion of the ladder. Similar safety has been reported in other studies, primarily among this low-risk population of patients with resolving allergies.

The original study that established that 77% of patients with milk allergy could tolerate BM, demonstrated key differences between the two populations of BM-reactive and BM-tolerant groups.⁴ Importantly, the BM-reactive group had higher baseline casein and milk-specific IgE and larger SPT result size. In addition, of those patients who were BM tolerant but unheated milk-reactive, no patients required epinephrine during unheated milk OFC. However, of the patients who were BM reactive, ~35% required epinephrine when challenged with BM ($p < 0.001$), which suggests a potential difference in baseline severity.⁴ More recently, a study of a cohort of patients with OFCs reported that half of the patients who were BE/BM reactive lacked mucocutaneous reactions during OFC and were significantly more likely to demonstrate lower respiratory tract manifestations.²⁰ Interestingly, these patients who were BE/BM reactive were also

Table 1 Factors associated with potentially favorable and unfavorable outcomes

Potentially Favorable	Potentially Unfavorable
Patient-specific clinical factors	
Younger age	Older age
Non-IgE-mediated allergy, <i>e.g.</i> , food protein induced allergic proctocolitis	Persistent IgE-mediated allergy
Previous mild, nonanaphylactic reactions	Severe, anaphylactic reactions
Nonasthmatic, or mild, controlled, treated asthma	Asthmatic
Small skin-prick testing result or low levels of serum specific IgE	Large skin-prick testing result or high levels of serum specific IgE
Declining skin-prick testing result or serum-specific IgE	Increasing skin-prick testing result or serum specific IgE
High previous reaction threshold	Low previous reaction threshold
Patient-specific nonclinical factors	
No language or comprehension barriers	Significant language or comprehension barriers
Access to emergency services	Poor access to emergency services or remote location
Dietitian or other health-care professional support	Lack of professional support
Willingness to use epinephrine	Apprehension to use epinephrine

IgE = Immunoglobulin E.

more likely to develop symptoms > 1 hour after completing the OFC. These findings could suggest a different degree of caution among these higher-risk populations.

Although reports of severe reactions are uncommon, they seem to be more frequently related among patients undergoing milk, and possibly egg, DATs.⁶ An Israeli analysis of a large, 1000-patient OIT cohort reported that milk OIT was a significant risk factor for both epinephrine-treated reactions (ETR) and a low rate of complete desensitization compared with non-milk OIT.²¹ Notably, the presence of asthma seemed to be a risk factor for ETRs in this milk-allergic cohort.

A recent review of near-fatal and fatal reactions to milk and egg DATs identified that all the patients were asthmatic, many with poor control or in the midst of an exacerbation.⁶ To the author's knowledge, near-fatal or fatal reactions have not been reported with DATs to other foods. Importantly, all of these very severe reactions were reported in a group of patients who seem phenotypically unlikely to outgrow these allergies, with high specific IgE and often older age. This group of patients included a 9-year-old Canadian girl who was asthmatic and who was implementing a modified BM ladder OIT approach.⁶ The fatal reaction had a delayed presentation and an exercise link. Unfortunately, previous anaphylactic reactions were treated with diphenhydramine, and her reaction was similarly linked to delays in symptom onset and a delay in treatment.

As such, several investigators have suggested factors that may be associated with the safer implementation of ladders.²² These factors include previous mild

reactions, declining specific IgE measurements, the absence of asthma, younger patients, etc. (Table 1). Clinically, many of these patient-specific factors are associated with a lower-risk phenotype that is likely to outgrow their egg or milk allergy, regardless of BE/BM ingestion. These factors, however, are not well defined, and one group suggests poor predictability of currently available testing to identify patients who are tolerant of BM.²³

The implications of patient selection may represent the fundamental factor that determines ladder success and safety. Use of a ladder for an individual at low risk and who is outgrowing his or her allergy may simply be ushering in an inevitable development of tolerance. Whether this is defined as low-risk OIT has not been agreed. However, using the exact same ladder approach in a patient with a high-risk phenotype can be, and has been, associated with disastrous outcomes and may be considered a more high-risk OIT.⁶ Clinicians must be careful not to translate their success with the predominant low-risk phenotype to the less common high-risk patient. A comparison of approaches is found in Table 2.

PROTOCOL SELECTION AND PROTOCOL STANDARDIZATION NEEDS TO BE IMPROVED

Standardization of ladders will be essential to evaluate the long-term success of milk and egg DATs.²² The preparation of EH products and allergenic changes inherent to the foods in egg and milk ladders can lead to highly variable delivery of allergenic protein

Table 2 Comparison between dietary advancement therapies (presented as overview, not as specific guidelines)

	Baked	Ladder	Baked OIT	OIT
Who	Low risk phenotype	Low-risk phenotype	Clinical trial	High-risk phenotype
How	Extensively heated baked product, <i>e.g.</i> , muffin	Progressive protocol, <i>e.g.</i> , muffin-pancake-cheese-yogurt-milk	Careful, precise protocol specifically escalating baked milk or egg protein amounts	Careful, precise protocol specifically escalating non-baked milk or egg protein amounts
Frequency of ingestion	Daily to multiple times a week	Daily to multiple times a week	Daily	Daily
Follow up	Every 6–12 months, with the introduction of new products, potentially in the office	Every 3–12 months, with the introduction of new products, potentially in the office	As per trial protocol with dose increases in the office	Every 2–4 weeks as per protocol, with dose increases in the office
Supervision required	Instructions provided with consideration to risk mitigation approaches	Instructions provided with consideration to risk mitigation approaches	Close supervision as per protocol with risk mitigation approaches	Close supervision as per protocol with risk mitigation approaches

OIT = Oral immunotherapy.

doses.^{24–26} Differences in heating time, temperature, recipes, matrix, and even unequal dispersion may contribute to these allergenic dose differences (Table 3). As in individuals at low risk and tolerant, these subtle variations may be well tolerated; patients at higher risk may be more sensitive to minor changes in protein dose. Unfortunately, these differences will be present even among similar types of foods, *e.g.*, a muffin.²² These challenges may be amplified by differences in types of food, a fundamental characteristic of a ladder.

While many types of ladders have been published, few have been validated in a large-scale randomized controlled trial, and some ladders show inconsistency in their recommendations. For example, a recently published milk ladder from a Canadian group suggested a progression to pancakes after successful tolerance of waffles.¹¹ However, the corresponding egg ladder suggests progression to waffle after pancake. This is a subtle difference, but it is quite probable that the degree of protein denaturing and thus allergenic protein present in both of these food products is different, and, in the patient who is sensitive or at high risk, this difference may contribute to reactivity.

Other elements of heterogeneity found in ladders include the patient's age, specific recipes, number of steps, physical location of ladder progression (clinic, hospital, or home), dietitian support, and selection of patients who are EH tolerant versus patients who are EH intolerant.

For patients who are BM intolerant, BM OIT approaches have been evaluated with carefully measured and standardized doses. Analysis of early Israeli data suggests that, in this high-risk group, only 21% could fully tolerate the target dose of 1.3 g of protein.²⁷ Of the remaining patients, this failed in 72% because of IgE-mediated reactions. However, tolerance to unheated milk was noted in those patients who were able to continue for 12 months. A more recent phase II randomized, double-blind, placebo controlled trial of BM OIT in this persistent phenotype was reported.²⁸ Of note, as with other forms of OIT, 20% of these patients treated with BM required epinephrine during the buildup phase, with exercise, menstruation, and illness being the most common reaction cofactors. In addition, similar to the previously noted OFC data, half of the ETRs were 2–3 hours after the dose. Encouragingly, the maximum tolerated dose of milk

Table 3 Potential sources of variation in baked products and ladders

Differences in heating time and temperature
Different recipes (including commercial variation)
Differences in matrix
Differences in dispersion
Differences in cultural foods
Differences in total amount of added milk or egg protein
Differences in total allergenic amount of milk or egg protein

increased dramatically among the patients who were actively treated versus those with placebo (4044 mg versus 44 mg of BM protein; $p = 0.0001$).²⁸ The recent Diagnosis and Rationale against Cow's Milk Allergy guidelines suggest that patients who are intolerant of BM should not at this time use OIT with BM until further research can determine the safety of these approaches.²⁹ Regardless, these standardized, known-dose protocols have not been as rigorously applied to ladders.

PATIENT PREPARATION AND COUNSELING ARE FUNDAMENTAL FOR SAFE IMPLEMENTATION

Fundamental to any home-based DAT is the adequate preparation of the patient and family. The information needs of patients undergoing formal OIT have been reviewed extensively elsewhere.³⁰ The understanding of the risks, benefits, procedures, risk-mitigation strategies, comorbidity (especially asthma) control, and other practicalities should be considered for these home-based procedures, where the family functions as amateur medical professionals.³¹ This education is especially important among patients potentially at higher risk.⁶

A recent survey reported that 84.3% of caregiver respondents received information about introducing BE/BM at home.³² Significant intercountry variation was reported. Of U.K. respondents, 49.2% reported receiving information from a dietitian, whereas no Canadian caregivers reported dietitian guidance. Similarly, the types of food and advice about specific recipes were variable. Although the amount and frequency of guidance desired by caregivers also varied, most respondents felt a need for some educational assistance.³²

It is suggested that patients who are considering a ladder should be given printed materials and, potentially, recipes to help with these approaches. The iMAP ladder has very specific recipes that allow a starting point for these families.⁷ Education about potential reaction cofactors, asthma control, illness management, compliance, and anaphylaxis management may also be beneficial in the context of a shared decision-making process.³⁰ The importance of adequate informed consent was also highlighted in a recent joint statement of the Canadian and British allergy societies.³³

LOOKING TO THE FUTURE

As ladders become more commonplace among the allergic population, further efforts are required to understand several key elements of these approaches. The optimal age of ladder implementation has yet to be determined. Although the acceptability and safety of ladders in infants have been reported, the long-term

effectiveness of this early implementation has yet to be determined.¹² Similarly, quantification of the specific amounts of the allergenic protein in the defined type of food item at each level of the ladder may help to determine the progression of these protocols more safely. Finally, efforts to improve communication strategies may expand on already reported checklists and educational initiatives.^{31,34}

CONCLUSION

Safety is the paramount goal for allergists, patients, and parents in all aspects of food allergy management. Improved standardization of ladders may improve the long-term outcomes of these patients through improved patient selection, protocol development, and education.

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