

ORIGINAL ARTICLE

Food Allergy & Anaphylaxis

Palatability of hypoallergenic formulas for cow's milk allergy and healthcare professional recommendation

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Abstract

Background: Cows' milk protein allergy (CMPA) is the most common food allergy in infants in the United Kingdom. Infants with CMPA who are not exclusively breastfed require a substitute hypoallergenic formula, which are perceived as having a poor palatability. This study compares the palatability of different extensively hydrolysed formulas (EHFs) and explores healthcare professional (HCP) expectations of how palatability impacts infants and their families.

Methods: Healthcare professional with experience of CMPA were recruited to take part in a home palatability test of four EHFs [Aptamil Pepti 1, Nutricia Ltd. (EHF W1); Althera, Nestle Health Science (EHF W2); Similac Alimentum, Abbott (EHF C1); Nutramigen LGG 1, Mead Johnson (EHF C2)] using a blind taste procedure. A randomised, complete block design was used to minimise order and carry-over biases. Participants completed a questionnaire about the impact of formula palatability on infants and their families.

Results: A total of 100 HCPs took part (51 dietitians and 49 general practitioners). Overall, whey-based lactose-containing EHFs were ranked the most palatable: EHF W1 by 77% of participants and EHF W2 by 20%. EHF W1 was liked significantly more ($P < 0.0001$) than the other formulas. The vast majority of participants agreed that better palatability would result in an increased chance of non-rejection (96%), more content families (92%) and decreased healthcare costs (90%).

Conclusion: Amongst HCPs who manage infants with CMPA, whey-based lactose-containing EHFs were ranked the most palatable. HCPs expected that good palatability would result in better acceptance, more content infants and families, alongside decreased wastage and healthcare costs.

KEYWORDS

cow's milk protein allergy, healthcare professional, hypoallergenic formulas, palatability, taste perception

1 | INTRODUCTION

Cows' milk protein allergy (CMPA) is the most common food allergy in infants, estimated to affect 1.3%–2.9% of young children in the United Kingdom (UK).^{1,2} This allergy typically presents in the first few months of life when an infant is exposed to cows' milk,

resulting in symptoms affecting the skin, gastrointestinal and/or respiratory symptoms. Infants with CMPA who are not exclusively breastfed require a substitute hypoallergenic formula, which is broadly divided into two categories: extensively hydrolysed formula (EHF), which is either casein- or whey-derived, or amino acid formula (AAF), which is composed of pure synthetic amino acids.

Extensively hydrolysed formula contain proteins that have been enzymatically modified into shorter peptides, which reduces the number of conformational and sequential epitopes, thus reducing the allergenicity.³ This process, however, leads to the formation of bitter- and sour-tasting peptides, which have a volatile odour, meaning that these formulas are commonly perceived as having a poor palatability.⁴⁻⁸ Studies in infants have demonstrated that those older than seven months tend to dislike and reject these formulas, but are more likely to accept these if they have been exposed to them before 3.5 months.^{6,9} Attempts have been made to improve the palatability of some formulas by replacing part of the carbohydrates with lactose and sucrose.^{10,11} Manufacturing techniques for medical-grade lactose have ensured that these are not contaminated with milk protein, making them safe to use in CMPA.¹²

Healthcare professionals (HCPs), particularly dietitians, general practitioners (GPs) and paediatricians, play a central role in selecting the most appropriate formula for the infant with suspected or confirmed CMPA. Several international guidelines have been developed to outline different indications for the use of EHF and AAF.¹²⁻¹⁴ The choice of formula made by the HCPs should primarily be based on whether the formula has been tested in cows' milk allergic infants according to current guidelines, clinical presentation and nutritional composition. Palatability and age are important considerations for HCPs, as many infants present beyond the critical period for taste acceptance of these formulas and some may have existing feeding difficulties.^{15,16} In addition, previous studies in adults have highlighted perceptions of a variety of hypoallergenic formulas,^{4,7,8} which may also impact on the choice of formula. The aim of this study was therefore to assess the palatability of four different EHF suitable for CMPA with HCPs and to understand their perception about the impact of palatability on infants with CMPA and their families.

2 | METHODS

Dietitians and GPs were recruited from England, Scotland and Wales in November 2016, by an external independent medical market research agency (corporate members of British Healthcare Business Intelligence Association and European Pharmaceutical Marketing Research Association) using their own HCP database specifically for

this study. An equal number of GPs and dietitians were approached and were required to meet the following inclusion criteria to be eligible for the study.

- To be involved in the management of infants with CMPA
- To be familiar with EHF brands available in the UK
- To be practising HCPs for 2-30 years
- Not to have participated in any research on CMPA in the past 3 months and
- Not to have any personal dietary restrictions including allergies or be pregnant (which may affect taste).

Campden BRI (Chipping Campden, Gloucestershire, UK), an independent consumer research organisation, designed the study and managed the data collection and analytical process on behalf of Nutricia Ltd./A Early Life Nutrition (UK). All EHF available in the UK at the time of the study were included (Table 1). AAFs were not included for two reasons: EHF is, in most situations, the first-line treatment for CMPA¹³ and to limit the number of tasting episodes for HCPs. Participants completed a home use test, which involved the ranking of four different formula samples blind/unbranded. The four different formulas, shown in Table 1, included two whey-based and two casein-based EHF.

A randomised, complete block design was used to minimise order and carry-over biases across all participants (see Figure 1). A pack containing samples, palate cleansers and assessment materials was sent to each participant, along with detailed instructions regarding preparation of samples. Each sample was assigned a three-digit code and was supplied without any packaging or brand information. Participants were instructed how to prepare the samples and the palate cleansers. The samples were prepared in baby bottles and decanted into tasting cups, ensuring the three-digit codes on the bottles and cups matched that of the infant formula pouches. Participants assessed each sample by taking two sips, then ranking the samples in order of overall liking. A thorough palate cleanse was performed between each sample using diluted lime cordial followed by water. The assessment took approximately 10 minutes to complete.

After assessing the four EHF samples, participants were asked a series of questions about their opinion on the impact of EHF palatability on infants with CMPA and their families. They were shown six statements, shown in Table 2, to which they could reply "yes" or "no." All responses were captured electronically using an online test

TABLE 1 EHF included in the blind, home taste test by HCPs

Name (manufacturer)	Abbreviation	Protein	Carbohydrate Source	Amount of lactose
Aptamil Pepti 1 (Nutricia Ltd)	EHF W1	Whey	Lactose and maltodextrin	2.9 g/100 mL
Althera (Nestle Health Science)	EHF W2	Whey	Lactose, maltodextrin and sugars	3.8 g/100 mL
Similac Alimentum (Abbott)	EHF C1	Casein	Maltodextrin	N/A
Nutramigen LGG 1 (Mead Johnson)	EHF C2	Casein	Glucose polymers and modified corn starch	N/A

N/A, not applicable.



FIGURE 1 Flow chart to demonstrate methodology (Samples offered according to randomised block design for home use test. The EHFs were provided in one of twenty-four randomised counterbalanced orders)

questionnaire via a computerised programme (Compusense Cloud, Canada).

2.1 | Ethical Considerations

As this was an anonymised survey in adults, ethical approval was not required for the study, as per guidelines in the UK. Written consent, however, was obtained at point of recruitment and again at the beginning of the online survey. Participants received complete information on the objectives of the survey as well as the procedure of tasting. The HCPs partaking in the study did not receive any payment from the sponsoring infant nutrition company but were compensated by Campden BRI for their time and contribution. The external independent research company, Campden BRI, is accredited under ISO 9000 and ISO 17025, and consumer research is run in accordance with the Market Research Society Code of Conduct 2014.

2.2 | Statistical analysis

The data were analysed using XLSTAT (v. 2016, France) software. Descriptive statistics (including percentages), Friedman Analysis of Rank test followed by Tukey's multiple comparisons test and k-proportion tests followed by the Marascuilo procedure were used to analyse the data. A significance level of 5% was used for all statistical analyses.

TABLE 2 Statements provided to HCPs in relation to the impact of EHF palatability

Do you think that the palatability (pleasantness) of the EHF that you would prescribe to infants with CMPA would have the following effects?	Yes	No
1. Increases the chance of non-rejection		
2. Results in more content families		
3. Decreases wastage and healthcare costs		
4. Increases compliance		
5. Decreases switch to other formulas		
6. Results in more content infants		

3 | RESULTS

3.1 | Characteristics of participating HCPs

A hundred HCPs completed the study. The cohort included 51% dietitians and 49% general practitioners; 36% were male and 64% were below 45 years of age. Nearly half of participating HCPs (48%) have been practising for 11-20 years.

The majority of the HCPs taking part in this study (68%) were aware of all tested EHFs: 98% were aware of EHF W1 and EHF C2, 72% were aware of EHF C1, and 68% were aware of EHF W2; 58% had tasted an EHF before taking part in this study.

3.2 | Ranking of formulas for overall liking

Overall, whey-based lactose-containing EHFs were ranked better (ie, ranked 1st or 2nd) than casein-based EHFs (ie, ranked 3rd or 4th), shown in Table 3. EHF W1 was significantly preferred ($P < 0.0001$) to all other tested formulas. There was no difference in palatability between EHF C1 and EHF C2 ($P = 0.981$). Similar results were obtained across genders, professions and age groups.

3.3 | Perceived impact of palatability

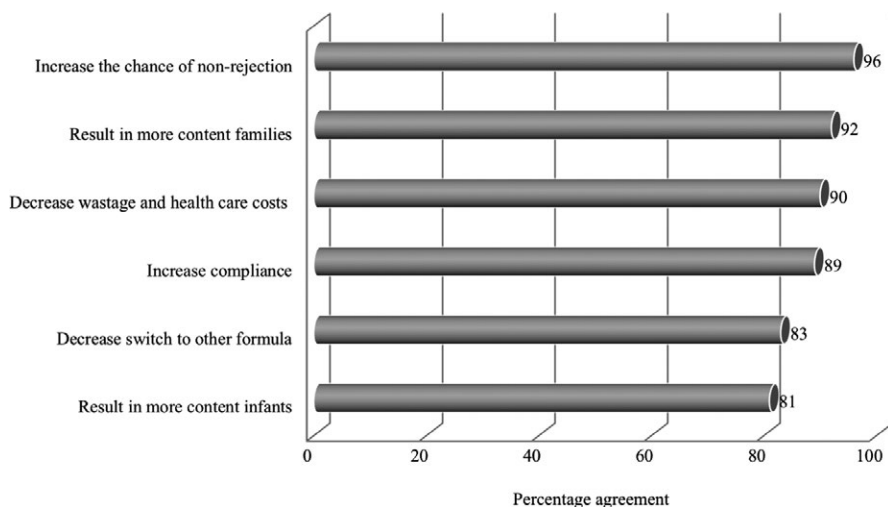
In response to the 6 statements about the perceived impact of palatability of EHFs on the infant with CMPA, their family and health-care system, the majority of HCPs thought that a better tasting EHF would result in an increased chance of non-rejection (96%) and more content families (92%) (Figure 2). In particular, a significantly greater number of HCPs perceived the palatability of the formula to lead to an "increased chance of non-rejection" as opposed to "more content infants" due to the perceived palatability ($P = 0.009$).

4 | DISCUSSION

This study set out to assess the palatability of four different EHFs used in the management of CMPA and to investigate HCPs perception of the impact of palatability. Using a simple ranking procedure,

TABLE 3 Ranking for overall liking by HCPs

done	Percentage of HCPs ranking formula 1st (most liked)	Percentage of HCPs ranking formula 2nd	Percentage of HCPs ranking formula 3rd	Percentage of HCPs ranking formula 4th (least liked)	Mean Rank
EHF W1	77	19	3	1	1.3
EHF W2	20	56	21	3	2.1
EHF C1	1	14	40	45	3.3
EHF C2	2	11	36	51	3.4

**FIGURE 2** HCPs perception of the impact of palatability, expressed in percentage

it was shown that both the first- and the second-ranked formulas by HCPs were whey-based lactose-containing EHF. Additionally, nearly all participants (96%) expected that a better tasting EHF would result in an increased chance of non-rejection, more content families (92%) and decreased healthcare costs and waste (90%). Whether the HCP's perception of a better taste improves acceptance of the hypoallergenic formula by the infant has not been studied. However, it is known from other healthcare domains that the HCP belief and perception is strongly associated with the beliefs of the patient.¹⁷ It may therefore be hypothesised that although there is not a direct impact on the infant's flavor acceptance, the parental attitude and acceptance of the new feed may be impacted through the perception and belief of the HCP, which may help with the introduction of a hypoallergenic formula.

The majority of infants with CMPA who are not breastfed will tolerate an EHF, which is reflected in all current guidelines.¹²⁻¹⁴ The choice of EHF should be based on best clinical evidence; however, taste and the acceptance of EHF is an important consideration, in particular in the older infant. Previous palatability research in older children and adults has found that casein-based EHFs tend to be rated most poorly overall.^{4,5,7,8} Pedrosa et al⁴ found a significant inverse correlation between peptide weight and taste rating. However, formulas within the same category were rated differently, meaning other factors such as the addition of sweeteners or flavourings, or specific nutrients, might have influenced taste perception. Specifically, it has been found that types of fat and carbohydrate are related to palatability.⁷ Miraglia et al⁷ reported that palatability decreased with increasing levels of total polyunsaturated fatty acids

and maltodextrins, but increased with increasing levels of saturated fatty acids and lactose.⁴ In the present study, both EHFs containing lactose were ranked the best tasting. These results are consistent with those obtained by De Jong et al,⁸ who also found that a whey-based lactose-containing EHF was ranked best tasting in HCPs in comparison with other hypoallergenic formulas.

For infants with CMPA who are not breastfed, selecting the most suitable and accepted formula is crucial. The flavour of a food determines its acceptability and modulates intake.¹⁸ Flavour may be more important in predicting intake in infants than adults, because they have less experience with food and are less influenced by cognitive factors which may influence intake (eg, food advertising).¹⁹ Early infancy is characterised as a sensitive period of time when learning about food preferences takes place.²⁰⁻²² Establishing acceptance of an EHF can be particularly challenging in those who are diagnosed at a later age, as bitter and sour tastes are more likely to be accepted in a taste-naïve infant.⁹ Following the first presentation of CMPA, infants in the UK had an average of 18 visits to their GP over 12 months, but those who remained on the same hypoallergenic formula had less visits.²³ Frequent changes in prescription of hypoallergenic formula are a major cause of excessive healthcare expenditure.²⁴ Therefore, in addition to the benefit of symptoms improvement, establishing an infant on an appropriate formula may also reduce wastage and healthcare costs, via saved appointment time.

The selection of a substitute formula for CMPA may also have long-term effects. The pattern of flavours that an infant is exposed to contribute to their unique pattern of food preferences, such that taste preference can be "imprinted" from infancy.^{18,25,26} Milk,

whether breast milk or formula milk, is the first food that infants consume and becomes the standard against which all other new foods and flavours are evaluated.²⁵ Therefore, the type, mode and taste experience of milk feeding may modify food preferences, nutritional intake and subsequently growth. Mennella & Beauchamp¹⁶ identified that formula type influenced infant's flavour preferences when assessed several years after their last exposure to the formula. Infants fed casein-based EHF were more likely to prefer sour-flavoured juices and broccoli at the age of 4-5 than those fed standard infant formulas. Maslin et al²⁷ found that consuming a substitute formula and/or an exclusion diet for CMPA in infancy has a long-term effect on the preference for bitter taste and some foods up to 10 years after the formula has been discontinued. These studies highlight the fact that infant formula choice in CMPA may have a long-term effect on eating habits, in addition to the more pertinent short-term outcomes of resolving symptoms and promoting tolerance.

There remain concern and resistance by HCPs, particularly in children with non-IgE mediated CMPA, to use a lactose-containing EHF. This is likely to have originated from the joint published guidelines from 1999 of the European Society for Paediatric Allergology and Clinical Immunology and the ESPGHAN, suggesting that products with little or no lactose may be beneficial in children with CMP-associated enteropathy.²⁸ This was followed in 2000 by the American Academy of Paediatrics²⁹ suggestion that "in infants with adverse reactions to food proteins and a malabsorptive enteropathy, a formula with highly reduced allergenicity (extensively hydrolysed formula or amino acid mixture) without lactose and with medium chain triglycerides might be useful until normal absorptive function of the mucosa was regained." Transport of disaccharides across the epithelial membrane requires the presence of an intact mucosal lining, and disruption by an inflammatory or structural enteropathy (such as in non-IgE mediated CMPA) may lead to a loss of normal transporters on the luminal facing apical membrane.³⁰ However, since then guidelines have not only been revised, to indicate that formulas with lactose are safe to use in all forms of CMPA, but a recent study by Meyer et al³¹ found that none of the children from a small cohort with non-IgE-mediated CMPA had secondary lactose intolerance. In addition, standard management of breastfed infants with a non-IgE-mediated CMPA, even in the presence of severe diarrhoea, is that breastfeeding should be continued. The main source of carbohydrates in breast milk is lactose and lactose has been shown to have a beneficial impact on calcium and zinc absorption, as well as the maintenance of a positive bacterial flora.^{32,33}

This study has several limitations; the primary limitation is the use of a panel of adults HCPs to assess the palatability of a product that is designed for and consumed by infants who have different taste perception. Previous research⁹ has assessed taste preference in infants using video analysis, volume consumed and maternal perception of preference. Although it would have been preferable to use this technique to assess palatability of EHF in infants with CMPA, such a study is extremely time-consuming and has ethical implications and the number of samples that can be tested in young infants is limited. Another limitation relates to the participants who

had awareness of the key brands of EHF available in the UK and some of whom (58%) had tasted an EHF previously. In an ideal study design, we would have recruited participants who had no prior taste exposure to the formulas; however, this was impractical given that we sought to recruit HCPs currently involved in the management of CMPA, with at least 2-year professional experience. This study did not collect data on which formulas HCPs had previously tasted, but the authors acknowledge that previous taste exposure may have biased the study. As tasting was done using a blind and fully randomised procedure, we believe that the bias has been limited. It is, however, possible that the odour of the formula could have influenced preference. In addition, the questionnaire about the impact of palatability did not include "no opinion/do not know" as an option, forcing HCPs to make a decision, even if they did not know or had no opinion on the topic. As we were collecting data on the overall palatability and acceptability of the formulae, rather than conducting a detailed sensory analysis, we did not specifically ask participants to rank the formula for bitterness. A more detailed sensory analysis study using a trained panel has been carried out by other researchers in our group and will be presented at the annual British Society for Allergy and Clinical Immunology Congress in 2018.³⁴ Finally, this study only assessed how the perception of taste of a hypoallergenic formula as experienced by a HCP may impact on formula choice and acceptance of the formula in a child with CMPA. This does not prove that there is a link of HCP taste preference of a hypoallergenic formula and child preferring the same formula, which needs to be established in future studies.

5 | CONCLUSION

In conclusion, this study has found that amongst GPs and dietitians dealing with infants with CMPA, a whey-based lactose-containing EHF was ranked the most palatable out of four different EHF. Furthermore, this study has also found that EHF palatability was expected to result in better acceptance and compliance, more content infants and families, alongside decreased wastage and healthcare costs. However, these findings should be interpreted with caution as it is not known if or to what extent HCP taste preference and opinion may influence parental and infant acceptance of hydrolysed formula.

COMPETING INTEREST

This study was funded by Nutricia Ltd./T/A Nutricia Early Life Nutrition, who employed an independent consumer research organisation to perform the study. KM, RM and AF received funding from Nutricia Ltd. for the write-up of the publication.

AUTHOR CONTRIBUTION

KM, AF and RM performed the critical appraisal of data and write-up of study. MC involved in the design of study and performing study.

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