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ORIGINAL RESEARCH

Tolerance of soya lecithin in children with non-immunoglobulin E-mediated soya allergy: a randomised, double-blind, cross-over trial

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Abstract

Background: Soya lecithin is present in a wide variety of foods regularly consumed by children, in the form of an emulsifier or stabiliser. Children with non-immunoglobulin (Ig)E-mediated allergies who commonly have to avoid milk and soya will have a significantly restrictive diet with reduced alternative foods if soya lecithin also has to be eliminated. The present study aimed to establish whether children with non-IgE-mediated gastrointestinal soya allergy react to soya lecithin in food products.
Methods: A double-blind, cross-over study was performed in soya-allergic children aged between 8 months and 5 years. Eligible children had their soya allergy status confirmed with a home challenge. Children were randomly assigned to either placebo or challenge dose of soya lecithin (1.5 g per day) in a custom-made biscuit. This was followed by a 1-week washout period and cross-over to another 1 week of challenge or placebo dose. Symptoms were recorded prior to commencing the study and at the end of each week's challenge.
Results: Twenty-two children, 16 boys, with a median age of 44 months (range 21–58 months) were recruited, although only 20 completed the full study. The median number of foods avoided in addition to soya was 3. Over the challenge period, the parents reported reactions in six cases: five cases (23%) to the placebo and one case (5%) to the challenge dose. There was no statistical difference ($P = 0.025$) between the groups.
Conclusions: One child with a non-IgE-mediated gastrointestinal allergy had a slight reaction to soya lecithin. Although single cases may react to soya lecithin, we suggest that soya lecithin should be included in children with this delayed allergy, unless they have a confirmed reaction to traces of soya within this emulsifier.

Introduction

Prevalence data indicate that approximately 2.2–5.5% of infants and young children are diagnosed with food allergies [(1)]. These allergies are classified according to their pathophysiology into immunoglobulin (Ig)E-mediated, non-IgE-mediated and mixed reactions. Non-IgE-mediated allergies affect mainly the gastrointestinal tract and skin and symptoms occur hours and sometimes days after the ingestion of the offending allergen [(2)]. The most commonly reported food allergens in children with non-IgE-mediated gastrointestinal food allergies are cow's milk

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and soya protein [3,4]. Although cow's milk is the most prevalent, data indicate that between 30% and 64% of children with a non-IgE-mediated cow's milk allergy and between 10% and 14% of children with an IgE-mediated cow's milk allergy may also present with a concomitant soya allergy [5,6]. The avoidance of soya in addition to cow's milk significantly complicates the elimination diet because soya is found in many processed foods [7]. In particular, soya lecithin is present in many foods that are otherwise free from common allergens. It was shown previously that, of the products labelled as containing soya, 52% contained soya lecithin and were usually avoided by parents, thereby reducing the choices of food significantly [8,9]

The allergenicity of soya lecithin has been a topic of debate in children, particularly in those with an IgE-mediated allergy. A study in 1998 found that the proteins present in soya lecithin have little antigenicity with respect to soya allergy [2,10], although several IgE binding proteins were found in soya lecithin and it was identified as a potential source of contamination in patients with this allergy [8]. Food products would generally not contain more than 1% of soya lecithin as an ingredient and, as a result, official bodies (i.e. The Food & Drug Administration and Food Allergy Research and Resource Program) have suggested that most IgE-mediated soya-allergic individuals do not react adversely to the ingestion of soya lecithin) [11].

Accordingly, many healthcare professionals, in contrast to parents and caregivers, have allowed selected patients with IgE-mediated soya allergy to consume soya lecithin because this soybean oil derivative is assumed to contain allergen proteins below the patient's threshold [9,10]. Although, in non-IgE-mediated soya allergy, the same pragmatic approach has been adopted, there is paucity of data regarding whether it leads to exacerbation of gastrointestinal symptoms on ingestion. The present study therefore aimed to determine whether children with non-IgE-mediated gastrointestinal soya allergy react to soya lecithin in food products.

Materials and methods

A randomised, double-blind, placebo-controlled, cross-over study was performed at Great Ormond Street Hospital for Sick Children NHS Trust. Ethics approval (Nr.14/LO/0746) was obtained from the National Research and Ethics Service in the United Kingdom (UK). The inclusion criteria for this study comprised children aged between 8 months and 5 years who had a confirmed (through protocolised home re-introduction) non-IgE-mediated gastrointestinal soya allergy and were also wheat and corn syrup tolerant because the challenge food contained both these ingredients. In addition, children included in the study were required to be stable in symptoms following the elimination diet and well managed from a dietary and medical perspective (no medication changes during the study). Patients who had commenced a new medication within 2 weeks of starting the study and those with soya-induced food protein induced enterocolitis syndrome were excluded from the study because there was concern regarding potential severe reactions occurring at home. Because endoscopies are not routinely performed, the study did not distinguish between children who had eosinophilic oesophagitis, food protein-induced enteropathy and other non-IgE-mediated food-allergic conditions.

Challenge food information

The daily dose of soya lecithin was calculated based on 3-day food diaries from a previously published study on non-IgE-mediated food-allergic children of foods that usually contained soya lecithin in the UK (i.e. breakfast cereals, confectionary, convenience foods, biscuits) [3,12]. The content of soya lecithin in commercial foods is usually <1% of total ingredients and the dosage was calculated at 0.75 g for children aged <1 year and 1.5g for children aged >1–5 years, which were considered to be the maximum amounts consumed in respective age categories. In addition, the aim was to keep refined sugar

Table 1 Biscuit ingredients and nutrition information

	Placebo (per biscuit)	Control (per biscuit)
Ingredients	Wheat flour, wholemeal wheat flour, rolled oats, vegetable oil, demerara sugar, sugar, raising agent (ammonium bicarbonate), salt, flavour	Wheat flour, wholemeal wheat flour, rolled oats, vegetable oil, demerara sugar, soya lecithin, sugar, flavour, raising agent (ammonium bicarbonate), salt
Allergy Information	Contains: wheat & gluten	Contains: wheat, gluten & soya
Energy (kcal)	55	57
Energy (kJ)	231	238
Protein	1.0 g	1.0 g
Carbohydrate	8.3 g	7.9 g
Of which sugars	2.4 g	2.3 g
Fat	1.9 g	2.2 g
Of which saturates	0.3 g	0.3 g
Of which trans	0.0 g	0.0 g
Fibre	0.5 g	0.5 g
Sodium	8 mg	8 mg
Lecithin		0.75 g

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content to <5 % in accordance with World Health Organization Guidelines [13] (Table 1).

The challenge foods were produced by DuPont Nutrition & Health (Solae, LLC, St Louis, MO, USA). Both soya lecithin and placebo challenge foods were packaged in separate sealed coded envelopes (daily dosage within each container) and coded according to the randomisation (Fig. 1).

Data collection and challenge procedure

At the baseline assessment, anthropometric parameters including weight and height were completed, as well as a thorough clinical examination of the skin, respiratory and gastrointestinal track, aiming to ensure that they were suitable to commence with the challenge at home. Children received a skin prick test applying solutions produced by Stallergens (London, UK) using a standardised skin prick test procedure. Skin prick tests were performed to soya and wheat, as well as to exclude an IgE-mediated reaction to the challenge food at home. Sensitisation to an allergen was defined by a measurement of 3 mm or more and patients who were sensitised were excluded. We also ensured that soya and soya lecithin, in addition to any allergens particular to the child, were completely eliminated from the child's diet prior to commencing the study and educated parents on this via written instructions from the British Dietetic Association Soy Free Diet Sheet. The challenge biscuits were coded for either active or placebo; when needed, the unblinded researcher identified the biscuits. The family was provided with two envelopes for each challenge week at the assessment appointment. Parents were given instructions on how to provide the challenge food product for their child to consume on a daily basis, including practical tips on how to mix it with foods if necessary (Appendix A).

Participating children completed a full week (7 days) of consuming the challenge/placebo food daily, followed by a 7-day washout period before crossing over to receive the alternate challenge food for another 7-day period. At the end of both arms of the study, the child exited the study (Fig. 2). When parents reported a reaction after week 1, the researcher was contacted and the protocol allowed for the researcher to extend the washout, if the reaction was deemed to be severe [14].

A previously published Likert scale symptom questionnaire in electronic format (www.surveymonkey.com) was used to monitor the symptoms during the study [2,15]. This questionnaire was completed four times during the study. The first questionnaire was completed at baseline prior to commencing the study and a further three times by the parents during the food challenge: after completion of 'week 1' (i.e. prior to commencing the washout period); prior to commencing 'week 2' of the challenge; and at completion of the study (Fig. 2). The parents received instructions on how to monitor their child's symptoms during the study at the first assessment visit. Symptoms in the questionnaire were ranked from 1 to 5, indicating what the child was feeling compared to the prior week after consuming the challenge biscuit on weeks 1 and 3 (Appendix B). Parents were required to contact the researcher if a reaction occurred during the study and questionnaires were reviewed by the researcher during the study to ensure accurate/correct recording of symptoms and to ensure that symptoms were not related to concomitant illness.

Statistical analysis

Data analysis was performed using SPSS, version 22 (IBM Corp., Armink, NY, USA). Patient characteristics are expressed in median and range. The nonparametric

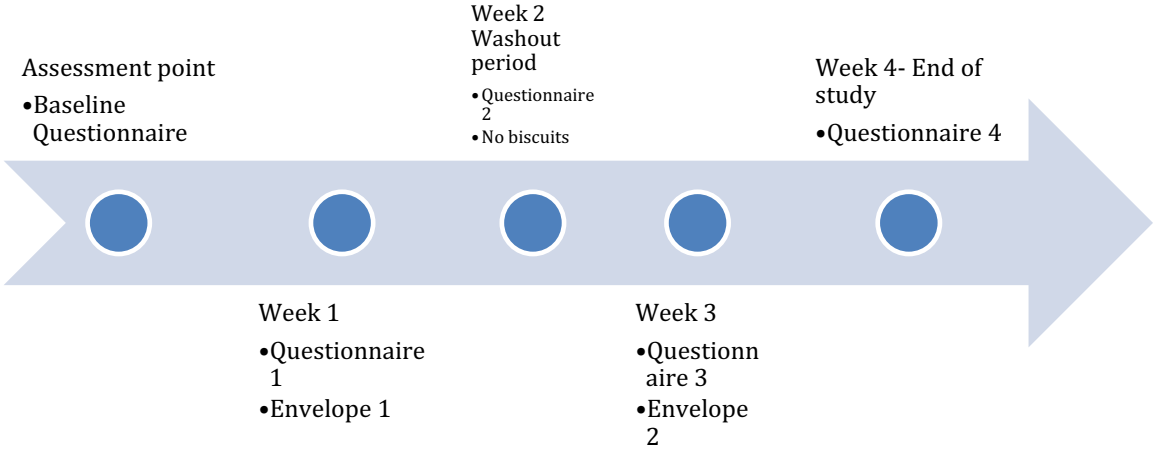

Figure 1 Study procedure.

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Figure 2 Examples of sealed and coded challenge biscuits.

Wilcoxon paired test was used to assess the differences in symptom score as reported by parents between the placebo and active soya lecithin biscuits. $P < 0.05$ was considered statistically significant.

Results

The study recruited 22 children, although only 20 completed the study, including 16 boys, and the median age was 44 months (range 21–58 months) (Table 2). No children were recruited between 8 and 12 months of age, and therefore all received a dose of 1.5 g of soya lecithin. Two children withdrew from the study because the parents reported reaction to the biscuits and they decided not to proceed with the study. One child had abdominal pain 2 days into the first challenge week, and the second child had diarrhoea 3 days into the first challenge week. These cases were deemed as an adverse event, and the external reviewer unblinded the patients at the end of the study. Both patients were taking the placebo biscuit at the time of the reported symptoms.

The majority of the recruited cohort avoided soya in addition to multiple other foods with the median number of foods avoided in the group being 3 (range 1–14 foods eliminated), as shown in Fig. 3.

Over the challenge period, in four cases, the parents reported reactions (Table 3): three (15%) to the placebo and one (5%) to the control. There was no statistical difference ($P = 0.72$) between the symptom scores of the placebo versus the active biscuits when assessing the paired samples.

Discussion

To our knowledge, this is the first study to establish tolerance of soya lecithin using a double-blind cross-over design in a non-IgE-mediated population with predominant gastrointestinal symptoms. In the study, we found no statistical difference in reported gastrointestinal symptoms between the placebo and active groups in the 20 cases completing the study. Indeed, more cases reported a reaction to the placebo. Two cases out of 22 withdrew within the first 2–3 days of the study; one parent reported symptoms of abdominal pain and the other reported symptoms of diarrhoea. Once unblinded, both children were taking the placebo. From our clinical experience, we

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Table 2 Patient characteristics (n = 20)

Age, median (range)	44 months (21–58 months)	
	8–12 months (dose 0.75g)	
	0	
	13–60 months (dose 1.5 g)	
	22	
Gender	Female	6
	Male	16
Medication	No	5
	Yes	17

List of Medication if used:
Nalcrom (n = 5), omeprazole (n = 5), ketotifen (n = 7), ranitidine (n = 1), calcium/ magnesium/ vitamin D (n = 1), azithromycin (n = 2), paracetamol (n = 2), domperidone (n = 1), flixotide (n = 1), sulfasalazine (n = 1), montelukast (n = 1), loratadine (n = 1), salbutamol (n = 1), lansoprazole (n = 2), cetirizine (n = 1), avamys nasal spray (n = 1), beclomethasone (n = 1), esomeprazole (n = 1)

These patients do not include children with food protein induced enterocolitis syndrome and, as a result of a lack of endoscopy, no differentiation between eosinophilic esophagitis and other non-immunoglobulin E-mediated conditions was available.

Table 3 Score of symptoms pre- and post-placebo and active challenges

Patient	Total score before	Total score placebo (/45)	Total score active (/45)
1	4	5	7
2	5	0	7
3	8	9	12
4	1	0	3
5	9	9	24
6	9	17	18
7	2	2	1
8	2	2	2
9	0	1	0
10	4	5	4
11	9	23	0
12	0	1	0
13	6	5	8
14	22	4	4
15	13	4	0
16	0	1	0
17	4	16	8
18	8	0	0
19	8	6	0
20	0	3	0
Average	5.7	5.7	4.9
Median	5	4	2.5

commonly see a change in gastrointestinal symptoms, irrespective of any changes in food intake, and therefore suspect that the reactions to the placebo simply reflected this. In one case, the parents reported an increase in the symptoms score from 9 to 24 on the active biscuit. There are no previously published data on a non-IgE-mediated soya lecithin allergy with which to compare our results. Renaud *et al.* [16] report a case of a 3 year old boy with IgE-mediated soya allergy who reacted to the ingestion of candy containing soy lecithin following a soy-free diet. Six months after the child followed a diet free from all soy lecithin-containing foods, a double-blind soya lecithin challenge was carried out, which triggered immediate diarrhoea versus no reactions to placebo. A similar case of an IgE-mediated soya-allergic child reacting to soya lecithin administered in a double-blind way was also reported by Palm *et al.* [17]. Using the reported single cases that react to soya lecithin with IgE-mediated allergies, it is plausible that the one child in our cohort experienced a real reaction to the soya lecithin.

Allergens in soya lecithin have been described in the literature. A study by Gu *et al.* [18] set out to describe IgE binding sites for soya lecithin: wide variation in soya protein was found in soya lecithin, ranging from 100 to 1400 ppm. Although significant IgE binding was found (in particular for a 39-kDa soy protein) that was strongly associated with oil bodies and a 2S albumin, the clinical significance was not studied [18]. Other studies investigated the major allergens in soybean and clinical significance with sera from IgE soybean-sensitive patients and it was suggested that these traces do not carry any clinical

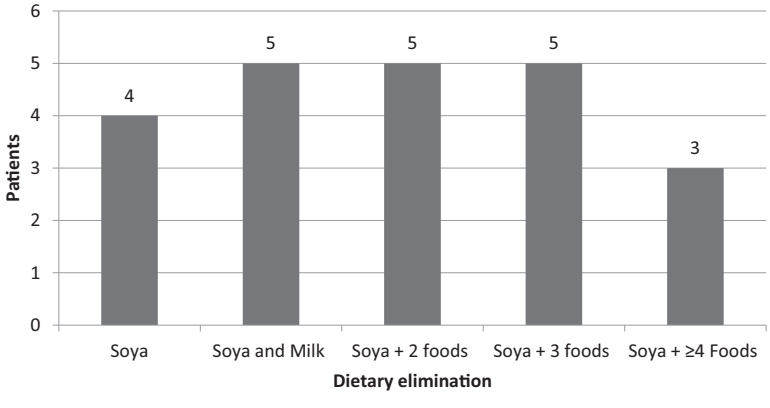

Figure 3 Dietary eliminations.

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relevance, and also that the proteins remaining in soy lecithin have little antigenicity with regard to soybean allergy [11,19–23].

Elimination diets, particularly with respect to the increasing number of foods that require avoidance, reduce the quality of life of families and children [2,24–27] The inclusion of soya lecithin in children with a soya allergy is often determined by the healthcare professional based on a risk assessment. In non-IgE-mediated cow's milk allergy, the data indicate 30—64% of children have a concomitant soya allergy [5,6]. Soya lecithin is added to numerous commercial products and, in our experience, many parents of children with multiple allergies in addition to soya have already provided their children biscuits and dairy-free chocolates containing soya lecithin without paying attention to its presence in the ingredient list and without any problems. Although we acknowledge that soya lecithin may contain traces of soya protein as found by Gu *et al.* [18], in our cohort of children, only one child had a possible reaction to soya. In the vast majority of non-IgE-mediated soya allergy, the inclusion of soya lecithin would be safe and any reactions are unlikely to be life threatening.

The present study has an unavoidable limitation such that the data are based on parent's self-reporting. However, we consider that the bias introduced with parental reporting is reduced by double-blinding and crossing over. In addition, the chosen dosage of soya lecithin could be raised as a limitation. The challenge dose by Palm *et al.* [17] was 100 mg, whereas we used 750 mg (0.75g) and 1500 mg (1.5 g), which was significantly higher. The content of soya lecithin in commercial foods is usually <1% of total ingredients and the dosage was calculated based on food diaries from a published cohort of children with non-IgE-mediated food allergies[27]. We ensured that our dose of 1.5 g represented the maximum dose that we observed in our patient cohort if they were to consume a variety of soya lecithin-containing foods on the same day. Therefore, in our opinion, the higher dose would ensure, a true reaction if it existed. Lastly, the low number of participants could also be raised as a limitation; however, as a result of the intensity of input for patients over the study period, our numbers are similar to those of Awazuhara *et al.* [10] who performed a study on 30 children on soya lecithin in IgE-mediated soya-allergic patients.

Conclusions

Soybean is one of the most common allergenic foods. Professionals in the health sector dealing with children with food allergies need to be able to advise them on the different ways of managing a soy allergy, including whether soya lecithin should be avoided or not. In the present study, one child out of 20 with a non-IgE-mediated gastrointestinal soya allergy had a reaction to soya lecithin. The results of the present study indicate that soya lecithin should not be excluded as part of any dietary elimination in non-IgE-mediated soya-allergic children. Although single cases may react to soya lecithin, we suggest that this is only eliminated if a child has a confirmed reaction because the inclusion of soya lecithin increases the variety of foods for the allergic child.

Acknowledgments

We thank the parents who participated in this study and ensured that their children consumed the suggested soya lecithin biscuits on a daily basis.

Transparency declaration

The lead author affirms that this manuscript is an honest, accurate and transparent account of the study being reported. The reporting of this work is compliant with CONSORT guidelines. The lead author affirms that no important aspects of the study have been omitted and that any discrepancies from the study as planned by the Bristol Research Ethics Centre (reference 14/LO/0746) have been explained.

Conflict of interests, source of funding and authorship

The authors declare that they have no conflicts of interest.
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Yara Gholmie was responsible for the collection of data, analysis and the writing up of the article. Adriana Chebar Lozinsky was responsible for the collection of data and the editing of the article. Kate Reeve was responsible for the collection of data and the editing of the article. Heather Goodwin was responsible for the collection of data and the editing of the article. Neil Shah was responsible for the editing of the article. Rosan Meyer was responsible for the statistical analysis and the editing of the article.

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Appendix A

Guideline on how to provide the biscuit

For infants of 8 months to 1 year, provide ONE biscuit per day

For children of 1 to 5 year, provide TWO biscuits per day

There are many ways to incorporate the biscuit in your child's diet

For mothers of infants of 8 months to 1 year

The biscuit is soft enough to be crumbled with your fingers and can be mixed dry with:

- Mashed/pureed fruits (homemade or commercial)
- Baby rice or baby cereal
- Mashed and mixed with hypoallergenic formula/suitable alternative milk

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• Mashed starchy food such as potatoes, rice, couscous, quinoa
• Suitable yogurt for child's allergy (i.e. coconut yoghurt, pea protein yoghurt)

The biscuit should be eaten entirely throughout the day; therefore, it can be portioned in different meals

For example, one biscuit can be divided into two snacks:

Day 1:

Morning snack: ½ biscuit + ½ banana
Afternoon snack: ½ biscuit + suitable yogurt/dessert (see above)

For mothers of children of 1 to 5 years

The biscuits can either be crumbled with your fingers or added to your child's food:

• Suitable yogurt (see above)
• Breakfast cereal
• Deserts: it can be used as a crumble topping for any warm winter desert
• Mashed potatoes
• Crumbled into bolognaise sauce/other textured sauces

If unaware, the child will not feel any major difference in the accustomed taste of the foods to which the biscuit was incorporated

The biscuit can also be eaten as a snack throughout the day, if the child accepts it

What if my child does not eat the biscuit?

It is important to contact the dietitian if this happens to help you incorporate the biscuit in a way that is acceptable to him/her. You will also be allocated some spare biscuits for both challenge weeks, which will can be used if he/she drops the biscuit on the floor or does not consume all of the biscuit hidden in the food

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Appendix B

Symptom questionnaire during soya lecithin biscuit challenge

PATIENT NUMBER:							
Foods eliminated due to a proven food allergy?							
Challenge week:							
Any change in your child's symptoms:							
Yes:					**No**		
If YES, when did these occur? Day of challenge: Number of biscuits:							
Medication: please indicate if your child has started on any new medication?							
Yes:					**No:**		
If yes, could you provide us with the name of the new medication and dosage							
Name	Commenced(date)				Dosage		
Frequency							
General Health: please indicate whether your child has had any of the following during the challenge							
Cough/Cold:				Runny/Blocked Nose:			
Wheezing/Asthma:				Fever:			
Dry skin (eczematous):				Any rash:			
Symptoms: please indicate which symptoms your child experiences?							
	Please indicate the severity of the symptoms: none mild moderate severe						What **age** did it start:
Diarrhoea:(loose, watery, frequent stools)	0	1	2	3	4	5	
Constipation:(excessive straining, low frequency, hard stools)	0	1	2	3	4	5	
Vomiting: (unexplained vomiting, often associated with abdominal pain)	0	1	2	3	4	5	
Rectal bleeding:(bleeding from the bottom when passing a stool, fresh blood)	0	1	2	3	4	5	
Abdominal pain:(affects daily functioning such as school and sleep)	0	1	2	3	4	5	
Wind/flatus:(excessive burping and painful wind)	0	1	2	3	4	5	
Bloating:(bloated/extended stomach that is hard when pressed)	0	1	2	3	4	5	
Screaming/back arching:(screaming associated with back arching and kicking legs out straight)	0	1	2	3	4	5	
Food aversion:(pushes away food, gags, holds food in mouth, spits/throws food, cries during meals)	0	1	2	3	4	5	

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