Cow's milk protein allergy and other food hypersensitivities in infants

Dr Carina Venter reviews the diagnosis and management of food hypersensitivity, including cow’s milk protein allergy, in infants and young children

Cow’s milk protein allergy

Prevalence

Food hypersensitivity (FHS) usually manifests in early childhood and is caused mainly by eight foods: cow’s milk, hen’s egg, soy, peanuts, tree nuts, wheat, fish and shellfish.

The prevalence of FHS in 0–3 year olds ranges between 2.1–4.2%. The few studies looking at FHS as a result of cow’s milk consumption as a single food show that about 2.5% of children suffer from cow’s milk protein allergy6,9–14, with 2.0–2.5% in the UK6,14.

The prognosis of cow’s milk protein allergy is good, with about 45–50% of children having outgrown their allergy at one year of age, 60–75% at two years and 75–90% at three years5,15. It is most likely to persist in those with a strong family history of atopy, IgE-mediated reactions, and other food allergies such as to egg, soy, peanut or citrus fruits5,15,16.

Nomenclature

In 2004 the European Academy for Allergy and Clinical Immunology (EAACI) and the World Health Organization (WHO)4 published a guidance document for the nomenclature used in allergic diseases. This identifies food hypersensitivity as the umbrella term for food allergy and non-allergic food hypersensitivity (food intolerance). Food allergy is distinguished from other adverse reactions to food by a mechanism involving the immune system, whereas food intolerance does not involve the immune system. According to the type of reaction, children with food hypersensitivity will present with a specific clinical picture. In the case of cow’s milk hypersensitivity, for example, they may present with immunoglobulin E (IgE)-mediated symptoms such as urticaria or angioedema, and also with non-IgE-mediated gastrointestinal symptoms including food protein enteropathy or non-allergic FHS such as lactose intolerance (see Figure 1).

Introduction

It is not uncommon for parents to believe that their infants or children are allergic or intolerant to a food, which in the majority of cases will not be confirmed by a medical diagnosis. False negative diagnoses can lead to the risk of ongoing symptoms with further and possibly severe reactions. False positive diagnoses, on the other hand, can lead to unnecessary restrictions on lifestyle and possible diseases from nutrient restriction1–3. For some of those with a true diagnosis, these allergies or intolerances could be life-threatening or have a substantial impact on the quality of life.

Appropriate dietary counselling and advice is needed to reduce the burden on the health system, as well as for the health and safety of the infant and child.

Key words:

food allergy; food intolerance; cow’s milk protein allergy; lactose intolerance; diagnosis; management

ABSTRACT

Food hypersensitivity (FHS) is the umbrella term used to describe both food allergy, which involves the immune system, and food intolerances, which do not. It is therefore important that the diagnosis is made by a specialist health care professional such as a paediatrician or allergist. Some experienced dietitians and health visitors may be able to assist in making a diagnosis.

The diagnostic work-up includes a medical history and blood tests/skin tests (where applicable). A food and symptom diary followed by a special test diet to identify the foods causing the infant’s symptoms may also be needed. Once a diagnosis is made, dietary advice should be given to eliminate or reduce the intake of the offending foods. For cow’s milk hypersensitivity in infants, this will include choosing the most appropriate specialised infant formula.


Mixed pattern: IgE/non-IgE-mediated cow’s milk protein allergy

Gastrointestinal: Allergic eosinophilic oesophagitis, allergic eosinophilic gastroenteritis

Cutaneous: atopic dermatitis

Respiratory: asthma

Figure 1: Definition of cow’s milk protein allergy (adapted from Venter5)
Burden on the health system

Allergic diseases across all ages costs the NHS an estimated £900 million a year\(^\text{19}\), mostly through prescribed treatments in primary care, representing 10% of the GP prescribing budget. The Health Economy Data as presented by Professor Julian Guest\(^\text{20}\), lecturer in Pharmaceutical Medicine at The University of Surrey, indicates that it costs the NHS £23.6 million per year to manage cow’s milk protein allergy in children. Treating one infant with an extensively hydrolysed formula for one year is estimated to cost £1,000. Using an amino acid-based formula is estimated to cost £2,500.

Diagnosis of FHS

There are many routes to a diagnosis (or false diagnosis) of food allergy and intolerance, such as taking a clinical history, tests and food challenges, and food reintroduction\(^\text{21}\). Figure 2 summarises the roles of different health care professionals in the diagnosis and management of FHS.

1. Clinical history

The clinical history is relevant in the diagnosis of IgE-mediated FHS, non-IgE-mediated FHS and non-allergic FHS. Careful history taking and physical examination form the basis of diagnosis of FHS and are explained in Table 1.

2. Diagnostic tests

**Skin prick tests and specific IgE tests**

Both skin prick tests (SPT) and specific IgE tests are useful in the diagnosis of IgE-mediated food allergy, but not for non-IgE-mediated food allergy or non-allergic FHS. However, in most cases a health care professional cannot make a diagnosis of food allergy based on SPT or blood test alone (see below). There are now more specific clinical decision measures known as cut-off points for both SPT and specific IgE levels\(^\text{21}\) available in the literature. This indicates to clinicians whether a food challenge is needed, and the likelihood of the outcome being positive.

**Patch tests to food**

This test is used in the USA in the diagnosis of allergic eosinophilic disease\(^\text{22,23}\) (see Glossary) and in Europe for the diagnosis of atopic dermatitis\(^\text{22,24}\), but not generally in the UK. Although there are a few centres where this diagnostic procedure is used, the usefulness of the test is still debated and hence it is not widely used in the UK. The diagnosis and management of eosinophilic disease and food protein enteropathies are usually dealt with in tertiary centres.

3. Diagnostic exclusion diets followed by a food challenge or food reintroduction

For many patients, particularly those suffering from non-IgE-mediated allergy or non-allergic FHS, diagnosis can only be made by means of a combination of clinical history and dietary investigations (diagnostic exclusion diets) followed by a food challenge or food reintroduction.

Generally, all patients with either a history of immediate symptoms or positive SPT, specific IgE tests should be invited to a controlled setting, i.e. under a doctor’s supervision and in the presence of resuscitation equipment, for a food challenge\(^\text{21}\).

A diagnostic diet could involve exclusion of a single food such as cow’s milk, excluding a number of foods such as cow’s milk, hen’s egg and wheat for allergic eosinophilic disease\(^\text{25}\), a few foods diet or a specialised infant formula (see Table 2).

Dietetic expertise is of particular importance when dealing with infants’ and children’s diets and progress should be monitored. Food exclusion diets are usually followed for a period of 2–3 weeks, but in diseases with fluctuating patterns such as eczema it may be necessary to continue for up to six weeks.

Diagnosis of cow’s milk hypersensitivity

An international task force has recently published guidelines for the diagnosis and management of cow’s milk protein allergy (CMPA) in both breast-fed and formula-fed infants. These need to be adjusted for local use taking into account the health care system and health care provision in each country\(^\text{24}\). For a detailed discussion of this topic, see Meyer\(^\text{26}\).

Current guidelines for the UK are in progress, and are expected to include recommendations on the allergy care pathway including appropriate usage of amino acid-based formula and extensively hydrolysed formula. Meanwhile, in the absence of specific guidelines, the decision to use one of these formulae for diagnostic purposes is a clinical one and may differ between different centres, depending on individual clinical preference.
Management of FHS

The input of a dietitian is paramount in the management of food hypersensitivity (see Table 3 for details of a typical dietary consultation).

Avoidance

A commonly presenting dilemma in clinical practice is whether to advise patients to strictly avoid the identified food or allow them to have small amounts on a regular basis when tolerated. Blanket advice of complete avoidance is difficult to follow, has a huge impact on quality of life and may not be essential for those children who tolerate small amounts. It could also lead to even more serious reactions in some children if accidental ingestion occurs. Further evidence for the best approach of managing this common problem is needed.

Table 2: Different hydrolysed/AMino acid-based formulae available in the UK

<table>
<thead>
<tr>
<th>Formula</th>
<th>Hypoallergenic characteristics</th>
<th>Diagnostic use</th>
<th>OTC</th>
<th>Prescription</th>
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<tbody>
<tr>
<td><strong>Partially hydrolysed formulae</strong></td>
<td></td>
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<tr>
<td>Comfort 1 and Comfort 2 (Cow &amp; Gate)</td>
<td>Partially hydrolysed whey</td>
<td>Not recommended for diagnosis or management of cow’s milk protein allergy/intolerance</td>
<td>Y</td>
<td>N</td>
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<tr>
<td>Easy Digest (Aptamil)</td>
<td>Partially hydrolysed whey</td>
<td>Not recommended for diagnosis or management of cow’s milk protein allergy/intolerance</td>
<td>Y</td>
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<td><strong>Extensively hydrolysed formulae</strong></td>
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<tr>
<td>Pepti (Aptamil)</td>
<td>Extensively hydrolysed whey Contains prebiotics Contains almost 40% lactose and therefore more palatable – suitable for most children with secondary lactose intolerance, but could be a problem with primary lactose intolerance as it is not lactose-free</td>
<td>To be used in diagnosis and management of CMPA in infants with IgE- or non-IgE-mediated allergy who first presented with symptoms upon introduction of a cow’s milk formula without acute, severe reactions and/or growth faltering</td>
<td>N</td>
<td>Y</td>
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<tr>
<td>Pepti Junior (Cow &amp; Gate)</td>
<td>Extensively hydrolysed whey Clinically lactose-free Contains 40% medium chain triglycerides</td>
<td>To be used in diagnosis and management of CMPA in infants with IgE- or non-IgE-mediated allergy who first presented with symptoms upon introduction of a cow’s milk formula without acute, severe reactions and/or growth faltering</td>
<td>N</td>
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<tr>
<td>Nutramigen 1 and 2 (Mead Johnson)</td>
<td>Extensively hydrolysed casein Clinically lactose-free</td>
<td>To be used in diagnosis and management of CMPA in infants with IgE- or non-IgE-mediated allergy who first presented with symptoms upon introduction of a cow’s milk formula without acute, severe reactions and/or growth faltering</td>
<td>Y</td>
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<tr>
<td>Pregestimil (Mead Johnson)</td>
<td>Extensively hydrolysed casein Contains 54% medium chain triglycerides (fat malabsorption) Clinically lactose-free</td>
<td>To be used in diagnosis and management of CMPA in infants with IgE- or non-IgE-mediated allergy who first presented with symptoms upon introduction of a cow’s milk formula without acute, severe reactions and/or growth faltering</td>
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<td><strong>Amino acid-based formula</strong></td>
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<tr>
<td>Neocate (SHS) Neocate Advance and Neocate Active (over 1 year) Nutramigen AA</td>
<td>Elemental formula</td>
<td>To be used in diagnosis and management of CMPA in infants with IgE-mediated allergy:</td>
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<td></td>
<td></td>
<td>1. Who reacted to cow’s milk protein in breast milk</td>
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<td>Y</td>
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<td>2. With history of acute, severe reactions</td>
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<td>Y</td>
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<td>3. With growth faltering</td>
<td>Y</td>
<td>N</td>
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<td>4. Whose symptoms continued on an extensively hydrolysed formula</td>
<td>Y</td>
<td>N</td>
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<td>5. With multiple food allergies</td>
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<td>N</td>
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<td>And in infants with non-IgE-mediated allergy:</td>
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<td></td>
<td></td>
<td>1. Who reacted to cow’s milk protein in breast milk</td>
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<td>2. With growth faltering</td>
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<td>3. Whose symptoms continued on an extensively hydrolysed formula or despite maternal avoidance of cow’s milk</td>
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<td>4. Infants suffering with food protein enteropathy syndrome with severe symptoms may also benefit from an amino acid formula (AAF)</td>
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<td>5. Infants and children with multiple food allergies</td>
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<td>6. Gut impairment conditions requiring an elemental diet, e.g.:</td>
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<td>• Short bowel syndrome</td>
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<td>• Malabsorption</td>
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<td>• Intractable diarrhoea</td>
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<td>• Inflammatory diseases of the bowel</td>
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Table 3: Dietary management of food hypersensitivity

A dietary consultation will include:
1. Assessment of height, weight and dietary intake
2. Avoidance advice (Table 4), including understanding food labels
3. Advice to ensure the diet is nutritionally adequate by providing information on substitute foods, “free from” lists and special dietary products
4. Advice on practical aspects such as: cross-contamination, eating in restaurants, going on holiday etc. When travelling abroad, translation sheets and useful information can be obtained from www.allergyaction.co.uk or www.allergyuk.org or www.anaphylaxis.org.uk
5. Advice on suitable recipes, recipe books and adaptation of family recipes
6. Follow-up and reassessment to determine development of tolerance

Levels of avoidance

Levels of avoidance required are currently based on:
1. The type of FHS from which the patient suffers.
   - Most people with IgE-mediated food allergy need to avoid the food completely including trace amounts. However, some people are able to tolerate cooked egg even though they react to partially cooked egg (e.g. in lightly cooked scrambled egg) or raw egg (e.g. in mayonnaise). Some people are also able to tolerate heated milk products (e.g. in waffles and muffins) although they react to drinking pasteurised milk.
   - Some people with non-IgE-mediated food allergy may be able to tolerate small amounts of the food to which they are allergic.
Most people with non-allergic food hypersensitivity (lactose intolerance) will be able to include small amounts of the food in their diet with no adverse effects (see Table 4).

2. The characteristics of the particular food protein and its degree of allergenicity, e.g. all children with nut allergies need to avoid the food completely, whereas some people with egg allergy may be able to tolerate small amounts of cooked egg.

3. The natural history of the particular FHS, e.g. most children will outgrow their milk allergy, but only a few will outgrow their peanut allergy (see “Frequently Asked Questions” Box on p.133).

Management of cow’s milk hypersensitivity

In addition to management of other FHS, management of cow’s milk protein allergy requires the health care professional to choose the appropriate formula (see Table 2, Figure 3 and Figure 4).

The European Society of Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) and the European Society of Pediatric Allergy and Clinical Immunology (ESPACE) stipulate that a hypoallergenic formula should be tolerated by 90% of infants with CMPA, with a 95% confidence interval. This means that a formula can be considered as “hypoallergenic” if the vast majority of children with cow’s milk protein allergy (about 90%) will tolerate the formula and improve when using it. However, a small percentage (about 10%) may still be symptomatic and will therefore need an amino acid-based formula.

Advice for breast-feeding mothers

The first advice to the breast-feeding mother should always be to try avoiding cow’s milk or foods containing cow’s milk in her own diet. If the maternal elimination diet does not lead to any improvement of symptoms despite very strong evidence of cow’s milk protein allergy in the infant, the only alternative may be to advise the mother to stop breast-feeding and to recommend the use of an amino acid-based formula.

Choosing the most appropriate specialised infant formula

The choice of product depends on:

1. the age of the infant
2. the level of sensitivity to cow’s milk
3. the presence of co-existing allergies
4. the immune mechanism involved
5. (IgE-mediated or non-IgE-mediated)
6. the nutritional status of the infant (see Table 1).

Extensively hydrolysed formulae and amino acid-based formulae

As already mentioned, there are no clear guidelines in the UK regarding which formula (see Glossary) to choose. It is, however, recommended that an amino acid-based formula should be used when dealing with children with growth faltering, severe IgE-mediated cow’s milk allergy (history of anaphylaxis or breathing difficulties), severe eczema, or in children suffering from any type of eosinophilic disease or food protein enteropathy.

For all other types or presentations of cow’s milk protein allergies, an extensively hydrolysed formula can be used (see Figure 3 and Figure 4).

Extensively hydrolysed whey and extensively hydrolysed casein formulae

It is widely accepted that the palatability of extensively hydrolysed whey (eHF-w) formulae (Aptamil Pepti) is superior to extensively hydrolysed casein formulae (eHF-c) (Nutramigen). This is because hydrolysation of the whey protein produces a more palatable product than hydrolysation of the casein protein. For more on palatability, see “Frequently Asked Questions” Box on p.133.

In addition, prebiotics have recently been added to the eHF-w (Aptamil Pepti), and two studies using this prebiotic mixture indicate an increase in probiotics (bifidobacteria and lactobacilli), reduced growth of potentially harmful bacteria as well as a reduced allergic response and reduced recurrent episodes of upper respiratory tract infection during the first year of life.

These two industry-funded studies, published in creditable peer-reviewed journals, are accepted as convincing despite being on small numbers of infants. Although the eHF-c may be less allergenic than the eHF-w, both these formulae have been used successfully in clinical trials in infants suffering from: IgE-mediated cow’s milk allergy (without a history of anaphylaxis), colic and/or intractable crying, and eczema (see Figure 3 and Figure 4).

Soya formulae

Soya formulae are not recommended for infants under six months of age, due the amount of isolatemes that will be consumed per kg of body weight in this age group and the risk of developing peanut or soya allergy, though these risks may be small.

Soya formulae can therefore be used in infants not allergic to soya after the age of six months, although soya is not considered to be the first choice of formula in many allergy centres. This is because infants who are allergic to cow’s milk often react to soya as well.

Despite these guidelines, the use of soya in the UK is still inappropriately high. Soya formulae, e.g. Fineso (Cow & Gate); Nurture Soya (Heinz); Isomil (Abbott); Prosobee (Mead Johnson); and Wysoy (SMA) may, however, be given to those infants who refuse extensively hydrolysed formulae.

Milk alternatives for children over two years of age

For children over two years of age with a nutritionally sound diet and sound nutritional status, cow’s milk alternatives include: soya milk; chufa milk derived from a succulent and trading under the brand name of Tiger White; almond milk; oat milk; coconut milk; quinoa drink (a milk derived from the quinoa plant); or potato milk. Rice milk is no longer recommended for children under the age of four-and-a-half years because of concerns about the arsenic levels in these milks.

Cautionary note: goat’s and ewe’s milk

The use of goat’s milk and ewe’s milk in the management of cow’s milk protein allergy is not...
Lactose to glucose and galactose. Inadequate levels and/or absence of lactase in the gut leads to an inability to break down lactose effectively. This leads to symptoms such as flatulence, bloating, diarrhoea and abdominal pain. Tests for lactose intolerance include the lactose tolerance test or the hydrogen breath test. An elimination diet followed by re-introduction is also a feasible way of diagnosing lactose intolerance; see www.lactofree.co.uk for a regimen that has been reviewed by the British Dietetic Association (BDA) (Table 5).

In summary, FHS is an adverse reaction upon ingestion of food which can either be immune mediated or non-immune mediated. The diagnosis of FHS can be difficult as mechanisms are often not completely understood by scientists and health care professionals. Multiple symptoms (which may be of immediate and/or delayed onset) and triggers can also be involved. Furthermore, there is no ideal diagnostic test.

Health care professionals often have different opinions about the use of tests and food challenges, which may be further complicated by the involvement of non-professionals performing non-validated tests. (For more on tests advocated by health care professionals. Multiple symptoms (which may be of immediate and/or delayed onset) and triggers can also be involved. Furthermore, there is no ideal diagnostic test.

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Further information

Infant and Toddler Forum
Introduction to food hypersensitivity. (Factsheet 4.2.)
http://www.infantandtoddlerforum.org/article_42+An+Introduction+to+Food+Hypersensitivity+_id-23.html

General guidelines on the management of food hypersensitivity. (Factsheet 4.3.)

British Dietetic Association
http://members.bda.uk.com/groups/paediatric/paediatricstatements/oysoprotein.pdf

Food challenge guide

Books

This Learning File is supported by an educational grant from Aptamil. It represents the independent views of the author and has been independently peer reviewed by JFHC.

The information was correct at the time of publication (July/October 2009) but please note new evidence becomes available.

This Learning File will cover upper respiratory tract infections including the role of infant feeding, and will be published in the September/October issue of JFHC.

Learning files

Box: Frequently Asked Questions

1. Do children outgrow peanut allergy?
It has been assumed that peanut allergy is for life, but latest research indicates that between 10%–20% of children could outgrow their allergy.4,42 However, it is important that the development of tolerance to peanut should be established by means of the appropriate tests and food challenges. To assume that the patient has developed a tolerance without the appropriated testing could potentially lead to severe and even fatal reactions.

2. Can we trust the information provided in the “allergen box” or “allergen statement” on a food label?
It is a legal requirement to include allergen information in the ingredient list. However, manufacturers are not legally required to list allergen information such as milk-free, egg-free etc on the label, although some do. Therefore, health care professionals should always advise patients to read and take note of the ingredient list and not to rely on the information box, as this may not give all the pertinent information.

3. Which formula is indicated in infants with food allergies who suffer from growth faltering?
An amino acid-based formula is the one that is usually recommended.

4. How should we deal with children who refuse an infant formula – primarily due to taste?
A major problem in the use of hypoallergenic formula is their poor taste. However, this is less of an issue for younger infants (less than six months of age) due to their relatively “naive” taste perception. In addition, research has shown that eHF-w is more palatable than eHF-c. Older infants, and infants who were previously breast-fed, commonly reject the introduction of the hypoallergenic formula. Therefore:
- Introduce the hypoallergenic formula as soon as possible, or if breast-feeding continue to breast-feed. In addition, make the transition gradual by the incremental mixing of the milks.
- Offer the hypoallergenic formula as the only fluid source
- If the infant is above six months, introduce the formula in a feeder beaker that has good flow (avoid beakers with valves as this prolongs contact of the fluid with teeth and could cause dental caries or decay)
- Mask the smell with vanilla essence (a few drops only)
- Commercial milkshakes powders should be used as a last option as they could create preference for “a sweet taste”. If used, their concentration should be reduced over time until the formula is taken neat.

5. How do we deal with tests advocated by complementary and alternative medicine sources?

Alternative testing for food hypersensitivity can be divided into two main groups:
- 1. Tests which use the body’s “energy” such as Vagestalting (electrodermal testing), hair analysis, applied kinesiology, and the pulse test
- 2. Blood analysis tests include IgG testing, Antigen Leukocyte Cellular Antibody Test (ALCAT) and Food Allergen Cellular Test (FAC-test)

Scientific literature does not support the use of any of these tests.49,50 With reference to IgG testing, more research is required to see whether this also relates to food hypersensitivity.

References
http://www.bda.uk.com/resources/statements/SoyaStatement0309.pdf

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Allergic eosinophilic gastroenteritis. Eosinophilic gastroenteritis is characterised by the infiltration of eosinophils of the gastrointestinal tract. Eosinophils can infiltrate either the mucosa (gut wall) or the muscle. The stomach is the organ most commonly affected, followed by the small intestine and the colon.

Allergic eosinophilic oesophagitis. Eosinophilic oesophagitis is an allergic inflammatory condition of the oesophagus, caused by an infiltration of the eosinophils. Symptoms are swallowing difficulty, food impaction, and heartburn.

Amino acid-based formula. Amino acid-based formulae are made up from single amino acids derived from various sources depending on the formula used.

These amino acids act as the individual building blocks that make up a protein and are highly unlikely to cause an allergic reaction.

Extensively hydrolysed formula. These formulae are based on cow’s milk, soya or pork proteins. The proteins are broken down by means of enzyme splitting and filtration to provide a product with smaller protein segments (called peptides) that are less likely to cause an allergic reaction, i.e. the proteins are basically “chopped up” to provide peptides that are too short to cause allergic reactions in the majority of children with cow’s milk allergy.

Food allergy and food intolerance. Food allergy is caused by a protein interacting with the immune system, e.g. peanut proteins causing hives and swelling of the lips. Food intolerance is caused by substances in food other than food proteins with no involvement of the immune system, e.g. lactose in milk causing diarrhoea due to an inability or reduced ability to digest lactose.

Food protein-induced enteropathy. This is a disease seen in the small bowel of patients, mainly characterised by atrophy of the villi, caused by proteins other than gluten and with less extensive villous atrophy than is seen in coeliac disease. It is usually characterised by diarrhoea, mild-to-moderate steatorrhoea and weight loss.

Food protein-induced proctocolitis/enterocolitis syndrome (FPIES). FPIES is a disease of infants and young children that mimics food allergies. Inflammation is caused by the intestinal food protein-activated lymphocytes and results in increased intestinal permeability, malabsorption, dysmotility, emesis, diarrhoea, pain, and failure to thrive.

Hospitalisation for possible severe infection is common in children with FPIES and most children outgrow it by the age of three years.

Glossary of definitions used:

1. Which foods are most likely to cause FHS in young children?
2. What is the difference between a food allergy and a food intolerance?
3. From what age can soya formula be used?
4. Should all types of dairy products be avoided on a lactose-free diet?
5. Are partially hydrolysed formulae such as Comfort or Easy Digest appropriate to be used for infants with suspected cow’s milk protein allergy?

Extensively hydrolysed formulae such as Comfort or Easy Digest are recommended for diagnosis or management of cow’s milk protein hypersensitivity and are aimed at avoiding minor digestive issues in otherwise healthy infants.

The text is based on evidence from allergy and intolerance and is aimed at easing minor digestive issues in otherwise healthy infants.

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