Fighting Food Allergy With Food: Eleven-Year Experience With Oral Immunotherapy For Food Allergy (OIT)

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ABSTRACT

Rationale: The components of agricultural products vary due to variations in growing conditions and harvest time. Protein concentration standardization of OIT foods appears to be a rational scientific approach to food allergy treatment. There is, however, no study demonstrating that variations in the concentrations of allergenic proteins during OIT are a cause of treatment associated adverse events (AEs).

Methods: Retrospective record review of patients receiving POIT approved by the North Texas IRB. OIT was administered according to modifications of previously reported protocols.

Results: 862 food allergic patients have been treated with eighteen different commercially available foods. For two foods, a single product was used for desensitization. Eight foods routinely used two different products, five foods used three products and three foods used more than three products. With the notable exception of wheat, OIT AEs were not associated with changes in food product.

Conclusions: The only common factor among the different products is an equivalent total protein content based on the <u>USDA Nutrient Database</u>. If product variations don't cause AEs, then the clinical impact of variations between different samples of the same product are trivial and don't make a difference. OIT product standardization solves a theoretical problem that doesn't exist in the real world. Requiring OIT product standardization will increase costs and postpone the availability of treatment. It is theoretically possible that variety in the foods used for OIT may provide a more appropriate desensitization reflective of the foods that may be encountered by desensitized patients.

INTRODUCTION

- Desensitization by oral immunotherapy is effective for most patients.
- Allergy to many different foods has been successfully treated with OIT.
- Concerns have been expressed that because foods are biologic products, they are subject to natural
 variations in protein content due to growing conditions and processing methods. Therefore, foods used for
 OIT should be "standardized."
- The only currently available "standardized" food was developed over more than ten years at a cost of hundreds of millions of dollars.
- Clinical experience demonstrates that standard, off-the-shelf food is satisfactory for OIT treatment.

SUBJECTS

- We report data drawn from a retrospective chart review of 862 OIT-treated patients treated between 07/2008 and 07/2019.
- Patients with a proximate history of IgE mediated reaction to the OIT food were offered the opportunity to be treated with oral immunotherapy.
- No patient was excluded because of the severity of their previous reaction or the degree of positivity of the food specific IgE or skin prick test.
- In some circumstances, parents declined confirmatory challenges and patients were treated based on high food specific IgE alone.

METHODS

- Retrospective record review of patients receiving food oral immunotherapy at the Dallas Food Allergy Center (Allergy Partners of North Texas).
- The record review was approved by the North Texas IRB.
- Food OIT was administered according to previously reported protocols or modifications of those protocols.
- One patient was pretreated with omalizumab. No other medications were used for food OIT pretreatment.
- All food preparations were made from commercially available food products.

RESULTS

Foods Used For Oral Immunotherapy

| Food | Escalation Dosing Foods | Maintenance Dosing Foods | | |
|----------------|------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|--|--|
| Peanut | Peanut flour, Bamba, peanuts, M&M's, Reese's Pieces, Tru-Nut, PB2, flavored PN butter | Peanut flour, Bamba, peanuts, M&M's, Reese's Pieces, Reese's Minis, Tru-Nut, PB2, PN butter | | |
| Egg | Liquid egg white | Liquid egg white, egg white powder | | |
| Milk | Whole milk | 2%, whole milk | | |
| Almond | Almond milk, almonds | Almonds, butter, milk | | |
| Brazil nut | Brazil nut flour, nuts | Brazil nut flour, nuts, butter | | |
| Cashew | Cashew flour, nuts, butter, milk | Cashew flour, nuts, butter, milk | | |
| Hazelnut | Hazelnut flour, hazelnuts, butter, milk | Hazelnut flour, hazelnuts, butter, milk | | |
| Macadamia nut | Macadamia nut flour, macadamia nuts | Macadamia nut flour, nuts, butter | | |
| Pecan | Pecan meal, pecans | Pecan meal, pecans, butter | | |
| Pistachio | Pistachio flour, pistachios Pistachio flour, pistachios, butter | | | |
| Walnut | Walnut meal, walnuts, butter, milk | Walnut meal, walnuts, butter, milk | | |
| Coconut | Coconut flour, shredded coconut | Coconut flour, shredded coconut, milk | | |
| Sesame seed | Tahini, unhulled sesame seeds, flour | Tahini, unhulled sesame seeds, flour | | |
| Sunflower seed | [®] SunButter, flour, seeds | ®SunButter, flour, seeds | | |
| Chickpea | Chickpea flour, chickpeas | Chickpea flour, chickpeas | | |
| Soy | Soy milk | Soy milk, soy beans | | |
| Rye | Rye flour, rye crackers | Rye crackers, flour, bread | | |
| Wheat | Vital wheat gluten replaces baked wheat products | Vital wheat gluten replaces baked wheat products | | |

Number Of Patients Treated With Each Food

| Foods Used for OIT | Patients Treated | • |
|--------------------|------------------|---|
| Peanut | 535 | |
| Milk | 141 | • |
| Cashew | 111 | |
| Egg | 98 | |
| Walnut | 68 | • |
| Hazelnut | 29 | |
| Sesame | 18 | • |
| Pecan | 16 | |
| Wheat | 16 | • |
| Almond | 11 | • |
| Pistachio | 8 | |
| Chickpea | 4 | • |
| Soy | 4 | |
| Brazil nut | 1 | |
| Macadamia nut | 1 | • |
| Coconut | 1 | |
| Sunflower | 1 | |
| Rye | 1 | |
| | | |

- Foods Used for OIT Patients Treated
 Peanut 535

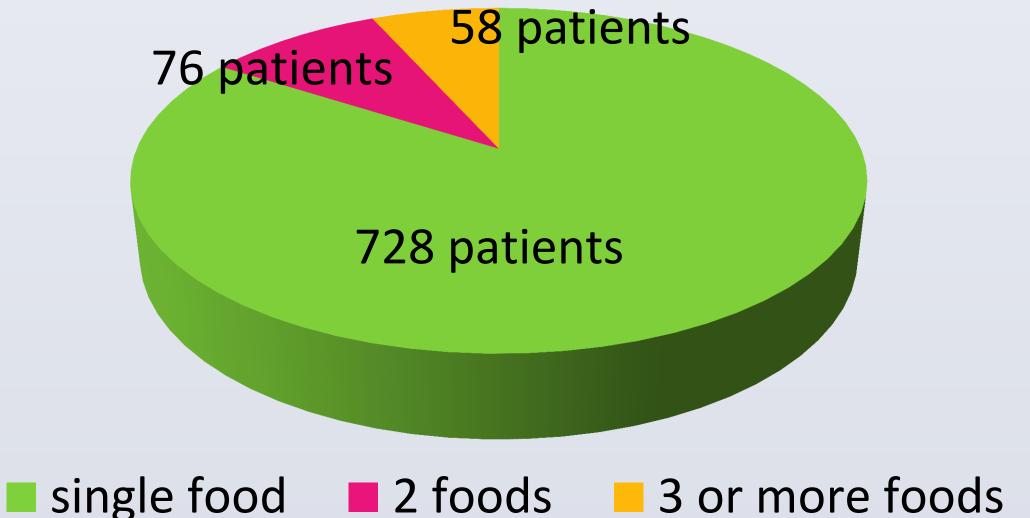
 Patients Treated to The initial protocols were based on common eliciting doses for peanut and milk.
 - As patients requested desensitization to additional foods, protocols for nuts and seeds were derived from the peanut protocol and protocols for other foods were derived from the milk protocol.
 - OIT foods are considered equivalent based on their labeled protein content.
 - Most OIT protocols involve the obligate use of more than one food as dosing amount changes.
 - Flours and meals that are used for very low doses may be unpalatable as the dose increases.
 - When the dose reaches more than 100mg of treatment food protein, taste aversion becomes an issue.
 - Even when there is not overt taste aversions, the boredom of eating the same food every day makes adherence more difficult.
 - Alternative forms of individual foods have been incorporated into protocols based on DFAC research and parental recommendations.

RESULTS

Desensitization Rate By Food

| | Started | Escalating | Discontinued/ Transferred care | Reached Maintenance | Reached maintenance (%) |
|-----------------|---------|------------|-----------------------------------|------------------------|-------------------------------|
| Egg | 82 | 12 | 9 | 61 | 89 |
| Milk | 127 | 3 | 32 | 92 | 75 |
| Peanut | 437 | 36 | 77 | 324 | 82 |
| Single tree nut | 64 | 12 | 9 | 41 | 83 |
| Multi food | 140 | 32 | 26 | 82 | 81 |
| Wheat/soy | 12 | 2 | 2 | 8 | 83 |
| Total | 862 | 97 | 157 | 608 | 82 |

Patients Treated With 1, 2 or 3/3+ Foods



CONCLUSIONS

- Desensitization to allergenic foods by oral immunotherapy is effective for most patientsCommercially available, off-the-shelf food is safe and effective for the treatment of food allergy.
- Protein concentrations, determined by the manufacturers, are sufficiently accurate to establish clinical equivalence.
- Under most circumstances, different sources of food protein may be used interchangeably as long as the allergenicity of the protein is maintained (e.g., peanut should be roasted, wheat should be unbaked).
- *Baking/cooking alters allergenicity and may make some foods unsuitable for OIT (e.g., baked wheat).
- Because of taste aversion and boredom, it is important to be able to use several foods during OIT to maintain adherence.
- So called "standardized foods" are a solution in search of a problem.

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