

Retrospective Study Comparing Allergy Release Technique[®] to Standard Management for Pediatric Peanut and Cow's Milk Allergies

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Abstract

Objectives: To compare standard allergy management (SM) to a new integrative treatment for food allergies, Allergy Release Technique[®] (ART), for effects on skin prick testing wheal diameter (SPT), IgE levels (allergen specific (SIgE) and total IgE (TIgE)), quality of life (QoL), anxiety, calcium intake, and allergen ingestion. ART includes multiple components, including skin conductance assessments at acupuncture points, exposure to radio frequency pulses, food desensitization, cognitive behavioral techniques, and post-treatment exposure to food allergens. Three hundred and seventy-seven children have participated in ART over the past 12 years.

Methods: Allergies had been documented in 2007-2015 (time 1) for both ART and SM groups (N=10 each), matched for age (7-17 years), gender, and food allergy (peanut or cow's milk). At study enrolment (time 2, 2016-2017), ART group had had weekly treatments (M treatment length=6.3 months). The SM group had been followed by a board-certified allergist for at least one year. An average of 4.56 years elapsed between time 1 and time 2 for both groups. At time 1 and 2, SPT, SIgE and TIgE were assessed; time 2 also included food challenges, food ingestion diaries, QoL and anxiety questionnaires.

Results: Wilcoxon signed-rank statistics revealed no significant differences between groups on any measures at time 1. At time 2, compared to the SM group, the ART group had lower SPT and self-reported impact of food allergy on QoL, higher allergen ingestion, and a greater decrease in SPT from time 1 to time 2 (p values <0.05; effect sizes, r=0.52-0.86).

Conclusion: ART is an integrative treatment resulting in smaller SPT, higher level of allergen ingestion, and lower impact of food allergies on QoL compared to SM. Results should be replicated using larger samples, a prospective design, disaggregating ART components, and comparing ART to oral immunotherapy.

Keywords: Food allergies; Electro-acupuncture; Anxiety; Cognitive-behavioral therapy; Electromagnetic stimulation; Desensitization

Introduction

Eight percent of children in the U.S. have food allergies, with often severe physical and psychosocial costs. Physical reactions range from nasal congestion and urticaria to life-threatening systemic anaphylaxis, and health consequences may include poorer nutrition (e.g. inadequate calcium intake in milk allergy patients) [1]. Psychosocial consequences often involve higher anxiety; stressful peer and family relationships; and lower quality of life, self-efficacy, and self-confidence [2-6].

Standard management for allergies typically involves (1) assessment of allergen specific IgE antibody levels (SIgE) and skin prick tests (SPT), (2) strict avoidance of offending foods, and (3) prescription of and education in the use of epinephrine auto-injectors and antihistamines. If SIgE decreases over time, food challenges are administered to test children's allergen tolerance.

Avoidance requires high levels of vigilance because 90% of food allergens are routinely found in the American diet, including cow's

milk, eggs, peanuts, fish, shellfish, soybeans, wheat, and tree nuts, making accidental ingestions commonplace. Thus, standard management does not constitute a cure, nor does it sufficiently reduce associated morbidities. More effective therapies are needed.

Although as many as 20% of families with food allergies turn to complementary and alternative therapies, including acupuncture, homeopathy, chiropractic, acupressure, massage, the Nambudripad Allergy Elimination Technique and natural food diets [7], there is no evidence that these approaches help children tolerate the food to which they are allergic.

Electro-acupuncture (applying weak electric current using electrodes placed at specific acupuncture points) and the Emotional Freedom Technique (EFT) involving tapping at acupuncture points have also not been tested for effectiveness with food allergies. However, along with transcranial direct current stimulation (tDCS) they have been found to improve mental health symptoms, including depression, anxiety, and PTSD [8-15].

One study indicated that electro-dermal responses differed in participants with and without environmental sensitivities after

chemical/environmental exposures [16], so it is worth investigating if electro-dermal measures might help in allergy assessment or treatment. Finally, cognitive behavioral therapy (CBT), incorporating psycho-education, coping, and problem solving skills has been shown to reduce anxiety and food allergy burden in mothers, but has not been investigated as a treatment to reduce allergic reactions [17-19].

Therapies that have effectively decreased food allergies involve oral immunotherapy (OIT), in which minute amounts of specific allergens are incorporated into a vehicle (e.g., apple sauce) and increasing doses are consumed on a daily basis, along with an extended maintenance phase that concludes with repeated food challenges [20].

Across multiple studies, OIT has resulted in decreased responses to SPT within several months of treatment and a decrease in SIgE over time after an initial increase [21-25]. The participant withdrawal rate from OIT trials ranges from 10% to 36% [20], partly because some patients experience allergic reactions while participating.

The objectives of the current retrospective study were to compare the efficacy of standard allergy management (SM) to a new treatment for food allergies, A.R.T. Allergy Release Technique® (ART) in 20 children ages 7-17 who had either cow's milk (dairy) or peanut allergies. ART integrates multiple components, including skin conductance assessments at acupuncture points, exposure to radio frequency pulses, food desensitization, cognitive behavioral techniques, and continued post-treatment exposure to food allergens.

ART was compared to SM for effects on allergen ingestion, daily calcium intake, SPT allergen wheal diameter (in mm), SIgE and total IgE levels (TIgE), anxiety and quality of life at two time points: time 1, before ART was administered and time 2, after ART had been administered to one half of the sample. ART and SM groups were matched for age, gender, and food allergy diagnosis. Stressors in the child's life during the year previous to study enrolment were also assessed in order to control for confounding variables.

Methods

Recruitment and inclusion criteria

The study was approved by the Boston Children's Hospital (BCH) Institutional Review Board. One hundred twenty children with peanut allergies, 27 children with milk allergies, 117 children with both milk and peanut allergies, and 113 children with other food allergies have participated in ART over the past 12 years, with a 7% withdrawal rate. The first step in recruitment was to invite families to participate *via* email, letters, or phone, whose ART treatment began after January 2012 and was completed at least 1 year and no more than 4 years, prior to study enrolment.

Interested families contacted the study coordinators. Participants were approached in reverse chronological order, working backwards from when they had finished treatment. Other inclusion criteria were having milk and/or peanut allergies documented by a board certified allergist between 2007-2015, at least one year prior to study enrolment (time 1).

In order to obtain the 10 ART families, 12 families were contacted, but two refused, one due to fear of the blood draw and the other due to prior negative hospital experiences.

The ten participants in the SM group were patients in the BCH Allergy Program. They were recruited with the following criteria: (1)

had documented milk and/or peanut allergies at time 1, (2) were under the care of a board certified allergist for at least the previous 12 months, (3) had expressed an interest in food allergy studies, and (4) had not received ART. SM participants were selected to match ART participants on the basis of gender, age and type of allergy. Of the 15 SM families who were identified as meeting matching criteria and contacted by email or phone, 11 consented to participate, and one of these did not complete all of the study requirements and was excluded from data analyses.

Participants

There were 10 children (7 males, 3 females) in each group, 6 with milk allergies and 4 with peanut allergies. The age range was 7-17 years, $M=11.80$ years, $SD=3.12$ years. Allergies had been documented at time 1 by a positive allergen SPT (wheal ≥ 3 mm larger than that elicited by the negative control) and/or a positive allergen specific IgE level (>0.35 kUA/L).

There were no significant differences as tested by Wilcoxon signed-rank and Chi-square tests between ART and SM groups in the number of children with a documented history of anaphylaxis ($N=3$ for ART and $N=4$ for SM); the number of foods to which participants were allergic (mean=5 foods; $SD=3.31$; $Mdn=3.5$ foods); or in history (ongoing and occurrences during past 12 months) of asthma, atopic dermatitis, or allergic rhinitis.

In the milk allergy group, 5/6 SM children and 3/6 ART children also had peanut allergies; 1/4 children in each of the SM and ART peanut groups also had milk allergies. The ART group had had ½ hour weekly sessions of ART lasting an average of 6.3 months, $SD=3.6$ months, range=3.5 to 16.1 months.

Procedure and measures

Written informed consent for parents and assent for children were obtained from all participants. Current study allergy assessment (time 2) for both SM and ART groups occurred between April to December 2016, with no significant differences between groups in the average amount of time elapsed between time 1 and 2 assessments; for SPT assessments: $M=4.12$ years; $Mdn=4.14$ years; Wilcoxon signed-rank test for group differences, $Z=0.79$, $p=0.43$ ($N=9$ ART and 7 SM participants); for IgE assessments: $M=4.89$ years; $Mdn=4.96$ years; Wilcoxon signed-rank test for group differences, $Z=1.22$, $p=0.22$, ($N=7$ ART participants and 9 SM participants).

For time 1, medical records were used to access SPT and IgE levels for both groups. For time 2, children in the ART group came to the BCH Division of Allergy and Immunology, for a visit that included SPT, *in vitro* IgE assessments measuring SIgE to milk and peanut using ImmunoCAP (Thermo Fisher Scientific, Waltham, Mass), TIgE and a food challenge in which they ingested 6 to 8 grams of milk or peanuts.

All ART children were given the food challenge because food diaries indicated they were ingesting allergens on a weekly basis, although only one ART child with a milk allergy met the Standardized Clinical Assessment and Management Plan (SCAMP) first iteration food challenge criteria: (for milk allergy: $SIgE \leq 2$ kU/L and SPT wheal diameter ≤ 8 mm and for peanut allergy: $SIgE \leq 0.7$ kU/L and SPT wheal diameter ≤ 5 mm) [26].

One child in the ART group refused the blood draw, so IgE levels could not be assessed. For the SM group, eight children had SPT or IgE assessments done at BCH within six months of study enrolment and

their medical records were used to access time 2 data; the other two participants came to BCH for SPT and IgE levels at time 2. None of the SM children was ingesting allergens according to food diaries, nor did they meet SCAMP food challenge criteria so they did not undergo food challenges at time 2.

Parents and children also completed several widely used, reliable and valid questionnaires either at their time 2 visit or at home, returning them by mail, which included:

- The Food Allergy Quality of Life Questionnaire (FAQLQ), assessing food related quality of life; versions for parents (17 items, 0 to 6 point scale), children ages 8-12 (24 items, 0 to 6 point scale), and adolescents ages 13-17 (23 items, 0 to 6 point scale) [27,28].
- The Child and Adolescent Survey of Experiences (CASE), assessing environmental stressors; versions for parents and children each 38 items, 0-3 point scale [29].
- The Spence Children's Anxiety Scale (Spence), assessing anxiety; versions for children (SCAS: 45 items, 0 to 3 point scale) [30] and parents (SPAS: 39 items; 0 to 3 scale) [31]. Both groups also completed a demographics form, a 3 day food diary and an allergen ingestion checklist.

ART treatment

ART was developed and delivered by author AT, a certified health and nutrition coach, and the treatment is detailed in Supplement 1.

The treatment has several components, primarily:

(1) Desensitization to minute amounts of food containing allergens, starting with tiny amounts touched to the face and lips for 4-6 weeks, followed by ingestion of poppy seed sized pieces gradually increased over a two to six month period, up to standard daily size servings that are maintained over time.

(2) Teaching CBT skills to manage anxiety (developed in collaboration with author LB), including repeating positive coping statements such as "I can be strong" and "I want to eat this food" and rewarding food exposures [32,33].

(3) Each week, using a galvanometer device (Bioscan system, International Health Technologies) with accompanying software (Bioscan MSA 141) to measure the electrical resistance between one of two acupuncture points on the fingers of one hand (in Chinese acupuncture, points Nervous system NE-1b⁺ and Allergy (upper toxicity), AL-1b⁺) and an electrode held in the other hand (skin conductance) when allergens are placed on a metal plate on the galvanometer or highlighted in the software library.

If low electrical resistance and impedance (or greater capacitance) is found as indicated by measurements above 55 on a 0-100 gauge, radio frequency pulses of approximately 556.8 ± 0.1 kHz are administered for 1 to 3 minutes through a device that is worn around the neck; and

(4) Tapping up and down the patient's spine after allergen or electromagnetic exposures, using the side of the practitioner's hand while patients take deep, slow inhalations and exhalations.

Hypotheses

Hypotheses were that at time 2, children in ART, as compared to children in SM, would (a) be able to ingest higher amounts of the allergen-containing food without having an objective allergic reaction during food challenges and as reported in weekly food diaries, (b) have

lower SIgE levels and SPT wheal diameter and a greater decrease in SIgE levels and SPT from time 1 to time 2, (c) have lower self-reported impact of food allergy on quality of life, and (d) ingest a higher percentage of the daily requirements for calcium if they had milk allergies. The number of positive and negative stressful events over the past year was also compared for the two groups.

Results

Analyses

Data analyses were conducted by staff that was blinded to participant group. Differences between ART and SM groups in major outcomes were tested using Wilcoxon signed-rank non-parametric tests, and results are displayed in Tables 1-4, which include group medians, Wilcoxon signed-rank test results (Z) and effect sizes (r values).

SPT differences between groups

Table 1 shows no differences in SPT wheal diameter at time 1, but significantly lower SPT at time 2 (Z=2.99, r=0.73, p<0.05) and a greater decrease in SPT from time 1 to time 2 (Z=3.34, r=0.84, p=0.001), for the ART group as compared to the SM group. These results were also significant when ART vs. SM group differences were analyzed independently for children with milk and peanut allergies.

Measure	ART group	SM group	Wilcoxon signed rank test			
	Median; N	Median; N	Z	p-value	r (effect size)	
Entire Sample						
Time 1: SPT, mm	15.00; 9	11.00; 9	-0.58	0.56	0.14	
Time 2: SPT, mm	7.00; 10	20.00; 7	-2.99	0.003	0.73	
Peanut Allergies						
Time 1: SPT, mm	14.00; 4	14.50; 4	-0.29	0.77	0.10	
Time 2: SPT, mm	9.00; 4	16.00; 3	-2.14	0.03	0.81	
Milk Allergies						
Time 1: SPT, mm	15.00; 5	11.00; 5	-0.85	0.40	0.27	
Time 2: SPT, mm	5.50; 6	22.50; 4	-2.35	0.02	0.74	

Table 1: Medians, Wilcoxon signed rank test values and effect sizes for skin prick testing (SPT) allergen wheal diameter.

SIgE and TIgE differences between groups

Table 2 shows no significant differences between the two groups in SIgE at time 1 or 2, or in SIgE changes over time.

Although TIgE differences were not hypothesized, there were no differences between groups for TIgE at time 1 or 2.

Measure	ART group Median; N	SM group Median; N	Wilcoxon signed rank test		
			Z	p-value	r (effect size)
Entire Sample					
Time 1: SIgE ^a	6.48; 8	20.30; 10	-1.33	0.18	0.31
Time 2: SIgE	3.34; 9	9.91; 9	-1.02	0.31	0.24
Time 1: TIgE ^b	791.00; 5	308.50; 8	-0.59	0.56	0.16
Time 2: TIgE	668.00; 9	310.00; 9	-1.37	0.17	0.32
Peanut Allergies					
Time 1: SIgE	4.27; 3	10.44; 4	-0.71	0.48	0.27
Time 2: SIgE	2.87; 4	9.91; 3	0 ^c	1.00	0
Time 1: TIgE	1250; 1	269; 3	-1.34	0.18	0.67
Time 2: TIgE	793.50; 4	310.00; 3	-1.41	0.16	0.53
Milk Allergies					
Time 1: SIgE	8.68; 5	23.25; 6	-0.91	0.36	0.27
Time 2: SIgE	3.34; 5	9.88; 6	-0.73	0.47	0.22
Time 1: TIgE	647.50; 4	964.00; 5	-0.49	0.62	0.16
Time 2: TIgE	668.00; 5	569.00; 6	-0.55	0.58	0.17

Table 2: Medians, Wilcoxon signed rank test values and effect sizes for IgE levels. ^aSIgE=Allergen specific IgE levels; ^bTIgE=Total IgE levels; ^cZ= 0 for Time 2 Specific IgE peanut groups because the mean ranks for ART and SM are identical: 4 and 4, even though the medians for the two groups are different.

Food ingestion differences between groups

Table 3 indicates that based on weekly food diaries, participants in the ART group had significantly higher levels of allergen ingestion

Measure	ART group (N=10)	SM group (N=10)	Wilcoxon signed rank test		
	Median	Median	Z	p-value	r (effect size)
FAQL-children ^a	0.17	3.73	-2.65	0.008	0.59
FAQL-parents	0.18	2.24	-3.07	0.002	0.69
Spence-children ^b	55.00	63.50	-0.87	0.38	0.19
Spence-parents	52.00	60.50	-0.80	0.43	0.18

compared to SM participants (Mdn=30.43 g for ART and 0.00 g for SM, Z=3.96, r=0.86, p<0.001).

Children with milk allergies in the ART group consumed a significantly higher percentage of daily required calcium than the SM group (Mdn=50% for ART and 30% for SM, Z=-2.33, r=0.52, p=0.02).

Further, the entire ART group was able to complete successful food challenges at BCH, consuming on average 6.80 g of the allergen (measured as a mean), whereas none of the SM children qualified to participate in food challenges.

Measure	ART group Median; N	SM group Median; N	Wilcoxon signed rank test		
	Z	p-value	r (effect size)		
Entire sample					
Food challenge-(g ingested)	7.00; 10	Test not done			
Allergen ingested weekly (g)	30.43; 10	0.00; 10	-3.96	0.001	0.86
Peanut allergies					
Food challenge-(g ingested)	6.50; 4	Test not done			
Allergen ingested weekly (g)	14.76; 4	0.00; 4	-2.46	0.01	0.55
Milk allergies					
Food challenge-(g ingested)	7.00; 6	Test not done			
Allergen ingested weekly (g)	62.55; 6	0.00; 6	-2.99	0.003	0.67
Calcium % daily value ^a	50.00; 6	30.00; 6	-2.33	0.02	0.52

Table 3: Medians, Wilcoxon signed rank test values and effect sizes for allergen intake. ^aThis is based on food and drink intake only; does not include supplements.

Quality of life differences between groups

Table 4 indicates that ART parents and children with both types of allergies reported significantly lower impact of food allergies on their quality of life as rated on the FAQLQ compared to SM parents and children (for parents: Z=3.07, r=0.69, p=0.002; for children: Z=2.65, r=0.59, p=0.008). The two groups did not significantly differ in general anxiety scores on the Spence or in the average intensity of stressors over the past year.

Measure	ART group	SM group	Wilcoxon signed rank test		
	Median	Median	Z	p-value	r (effect size)
CASE positive events-children ^c	12.00	11.00	-0.11	0.91	0.02
CASE positive events-parents	14.00	11.00	-0.69	0.49	0.15
CASE negative events-children	4.50	5.00	-0.80	0.43	0.18
CASE negative events-parents	3.00	2.00	-0.23	0.82	0.05

Table 4: Medians and Wilcoxon Signed Rank Test Values for Food Related Quality of Life (FAQL), Spence Anxiety Scale, and Child and Adolescent Survey of Experiences (CASE). ^aThe FAQL (Food Allergy Quality of Life Questionnaire) score is the mean of items (possible range = 0 to 6). Mean total scores on child and adolescent versions were pooled to derive the FAQL-children's score; ^bSpence (Spence Anxiety Scale), children's version, SCAS: 45 items, 0 to 3 point scale and parents' version, SPAS: 39 items, 0 to 3 point scale. Score reflects the sum of items; ^cCASE (Child and Adolescent Survey of Experiences): mean of 38 items, 0 to 3 point rating scale for how positive/negative each experience was.

Discussion

This retrospective study introduces a new treatment for children's allergies, ART, and compares SPT, SIgE, TIgE, general anxiety, food related quality of life, daily calcium intake and weekly allergen ingestion, in 10 children who participated in ART to 10 children in a standard management group. Groups were matched for age, gender and food allergy (either milk or peanuts). They did not differ in positive and negative life stressors, number of food allergies, or history of anaphylaxis, allergic rhinitis, atopic dermatitis, and asthma.

The groups were compared at two time points: time 1, before ART was administered and time 2, after ART was administered to ½ of the children. At time 2, the children who participated in ART, compared to SM, had significantly reduced their SPT wheal diameter, were able to complete a food challenge, and were able to eat foods they were formerly allergic to on a weekly basis. Children's daily intake of calcium was higher for children with milk allergies in the ART group compared to the SM group. There was no treatment effect for SIgE or TIgE.

Children and parents in the ART group also reported significantly lower impact of food allergies on quality of life at time 2, although there were no differences for general anxiety. Being able to eat previously avoided foods may have helped families feel more confident and less limited in participating in food-related social activities, e.g., eating in restaurants, but did not impact non-food related life anxieties.

While BCH and BU study authors do not endorse food allergen desensitization without medical supervision and follow-up, this study was conducted to better understand the efficacy of ART, a multi-faceted treatment that includes skin conductance assessments, exposure to radio frequency pulses, food desensitization, continued post-treatment exposure to food allergens, and CBT.

Findings from this retrospective study raise important questions about whether methods used in the ART treatment, such as CBT or exposure to electromagnetic stimulation, could be implemented to enhance the effectiveness of OIT conducted in medical settings. Although OIT and ART both enable children to safely ingest foods they reacted to pre-treatment, a review of the literature suggests that ART may have lower treatment burden compared to most OIT treatments, including (a) a shorter length of treatment [20] (b) lower

anxiety during and post-treatment [34] and (c) no requirement for accompanying injections, sometimes a part of OIT treatment [34].

However, additional investigation is necessary to confirm these advantages and to understand the immunologic mechanisms, including which of the ART components are driving the effects. Future research should disaggregate the components of ART to see which ones are necessary and effective and systematically compare ART to OIT.

Because this is a small sample, all results need to be replicated with larger samples. Other limitations of the study include the fact that this was not a randomized prospective study so some families who opted to participate in ART might differ in motivation or other variables that might affect allergy progression. We also have no data on allergic reactions for the two groups during the 4 years that elapsed between time 1 and time 2.

It will be critical to study the safety of this treatment, given the potential for allergic reactions during allergen desensitization and importance of prompt medical treatment/guidance. Because none of the participants in the SM group met criteria for food challenges at time 2, responses to food challenges could not be compared for the two groups, and neither group had participated in previous food challenges so changes in food tolerance over time could not be studied. Finally, ART was delivered by an experienced provider who may have developed special rapport with participants, perhaps affecting outcomes. Despite these limitations, ART is a new integrative treatment worthy of further study.

Conclusion

Children with peanut and cow's milk allergies who had participated in a new integrative treatment for food allergies, ART, had significantly smaller SPT, higher level of allergen ingestion, and lower impact of food allergies on quality of life compared to children who had been in standard allergy management. The efficacy and effectiveness of ART should continue to be investigated using larger samples, a prospective design, disaggregating individual ART components, and comparing ART to OIT.

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