Measuring What We Do

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Disclosures-None

Why Measure?

- Contributes to the literature in the private practice of OIT
- Enhances credibility of private practitioners performing OIT
- It’s fun and exciting to share this information especially with our private practice OIT community (but also … the academic community)
- Facilitates collaboration with other researchers

Practice-Based OIT QOL Study

- Recognized the impact of food allergies on QOL (comparative to that of other chronic diseases)
- Literature review of OIT (Limited data in 2010)
- Interested in examining clinical experience with OIT and focus on patients’/caregivers' perspective
- Review validated food specific QOL surveys and designed questionnaires for caregivers and adolescents

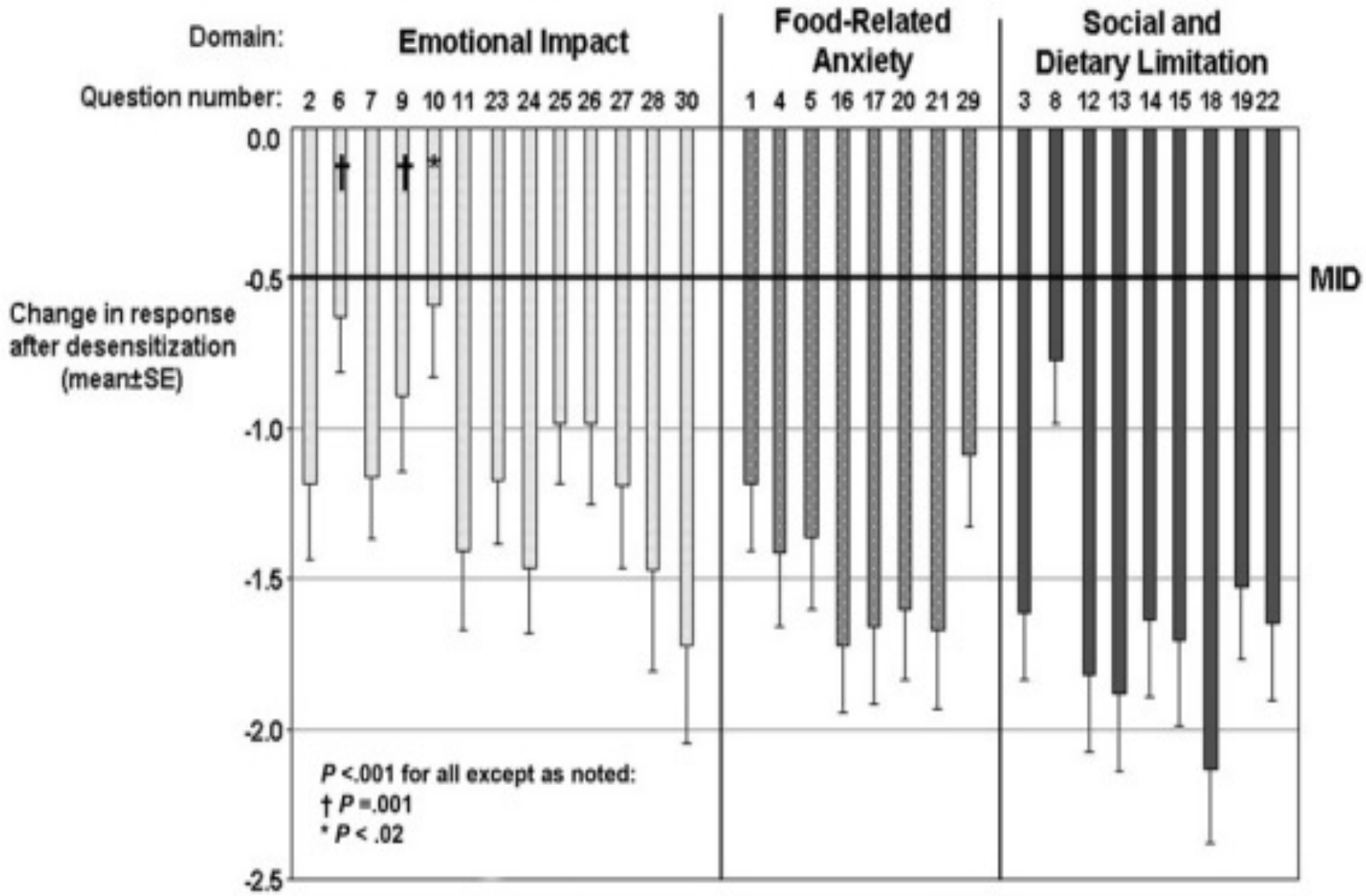

Fig. 1. Changes in 30-item parent quality-of-life questionnaire[23] by domain (n = 76) after desensitization to peanut compared with baseline. Changes in response to specific questions are grouped by domain (see eAppendix: A). A lower number indicates less effect on quality of life. MID indicates minimal important difference on a 7-point Likert scale.

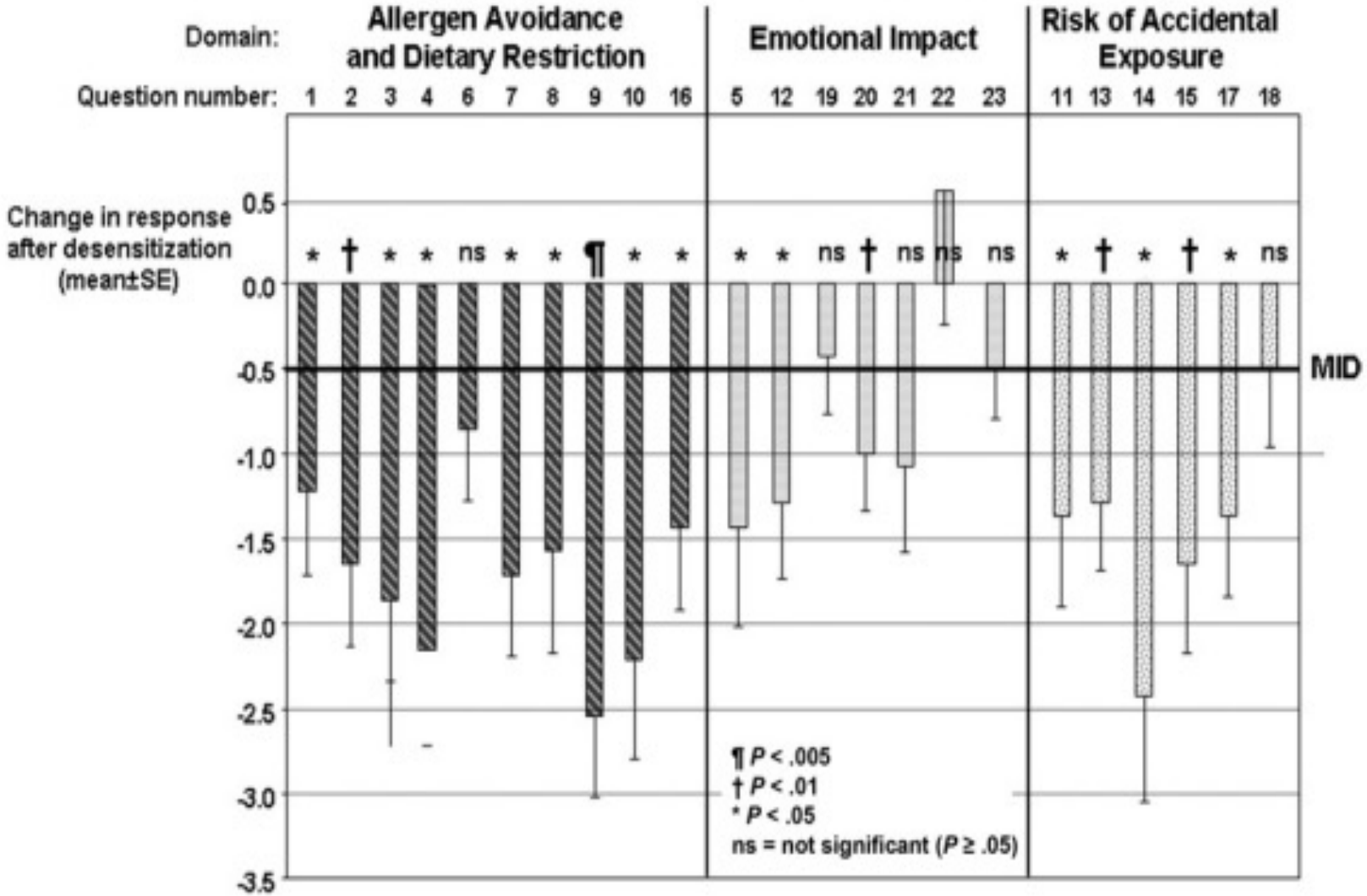

Fig. 3. Changes in 23-item adolescent quality-of-life questionnaire[25] by domain (n = 14) after desensitization to peanut compared with baseline. Changes in response t specific questions are grouped by domain (see eAppendix C). A lower number indicates less effect on quality of life. MID indicates minimal important difference on a 7-poin Likert scale.

Findings and Limitations

- Domains: Allergen avoidance, dietary restriction, risk of accidental exposure, emotional impact, food-related anxiety, and social and dietary limitations
- Significant improvement in QOL was found in all survey domains
- Observed teenagers' positive self reports
- Limitations-not a randomized/controlled study
- Subject to observational bias

Factor et al. Ann Allergy Asthma Immunol Nov 2012

Quality of Life of Food-Allergic Patients Before, During, and After Oral Immunotherapy

- Food Allergy Quality of Life Questionnaire-Parental Form (FAQLQ-PF) was administered to parents of 191 children aged 4 - 12 yrs
- FAQLQ-PF scores measured from OIT initiation to reaching full maintenance emotional impact [EI], food anxiety [FA], social and dietary limitation [SDL]; and total score
- Examined QOL in patients who completed the FAQLQ-PF 6 months after reaching maintenance

Epstein-Rigbi et al. J Allergy Clin Immunol Prac Feb 2019

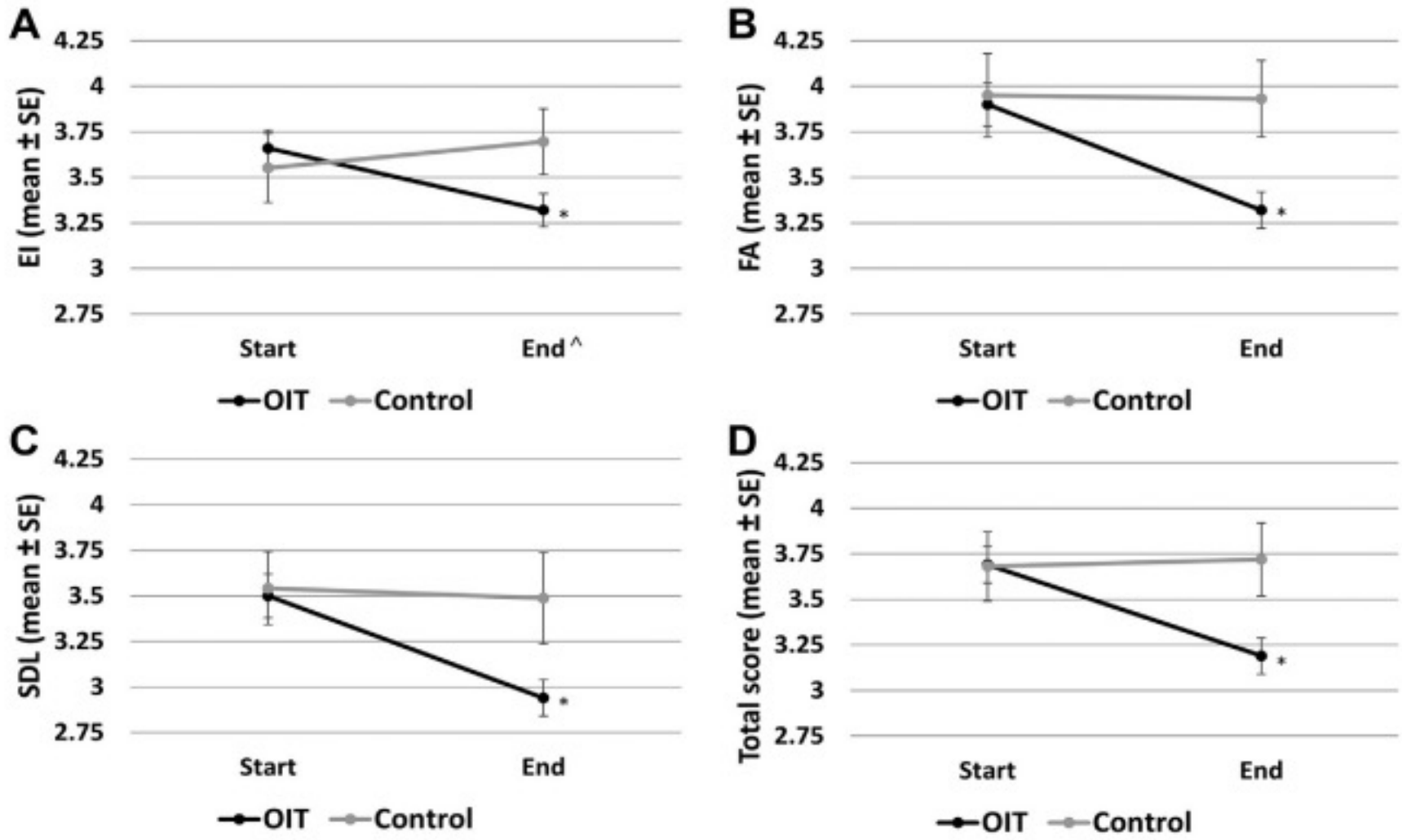

FIGURE 2. Changes in the FAQLQ-PF scores in OIT-treated patients vs controls from start to maintenance or treatment cessation: (**A**) EI, (**B**) FA, (**C**) SDL, and (**D**) total score. *Represents a significant change in the 2 time points during OIT treatment.

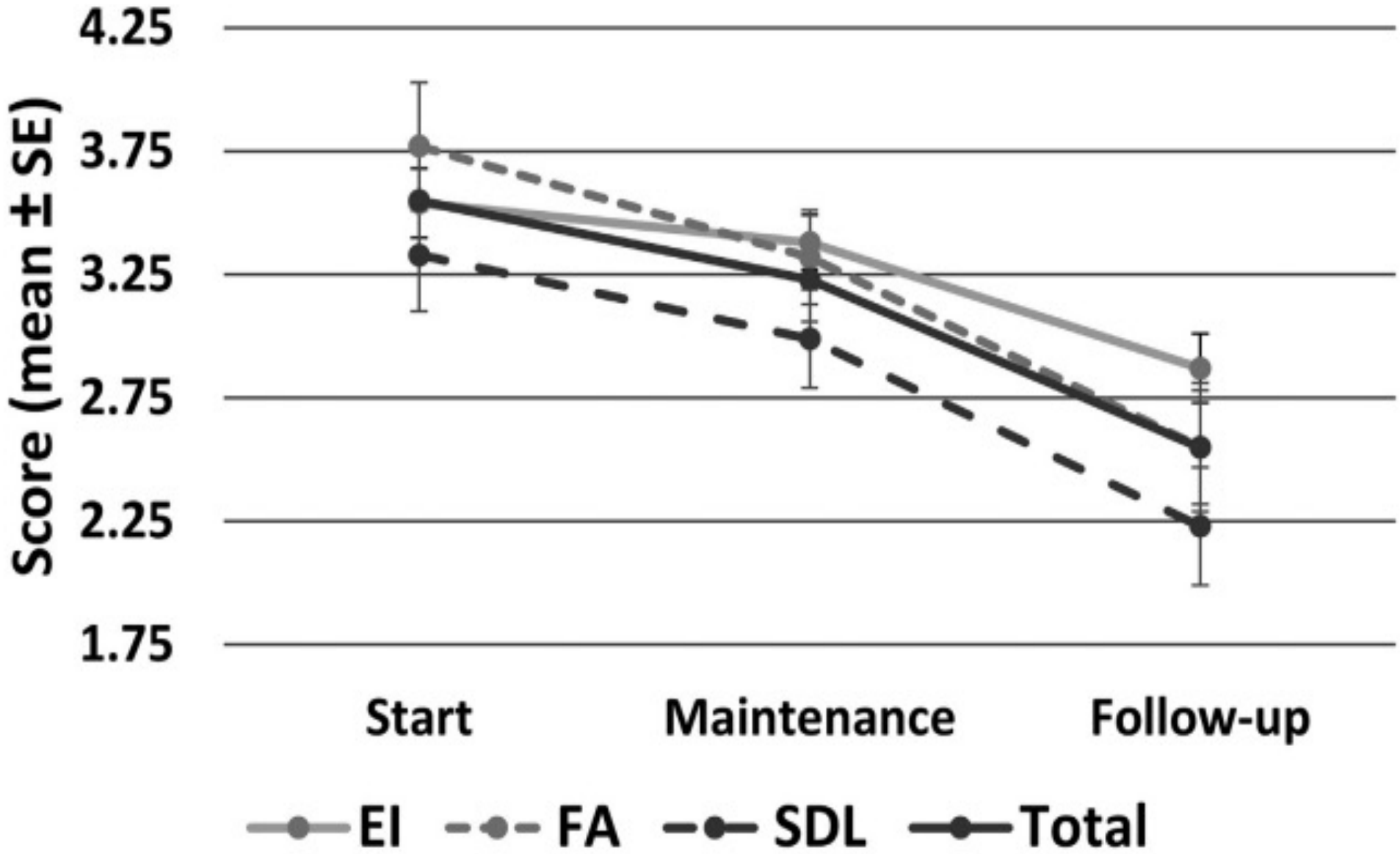

FIGURE 5. Changes in the FAQLQ-PF scores in OIT-treated patients from start to maintenance and then to follow-up in the EI, FA, SDL, and total score. Significant differences were found for FA, SDL, and total score between start and maintenance and for all domains from maintenance to follow-up.

Summary: Quality of Life

- Most (but not all) studies confirmed desensitization correlates with improvement in children's QOL as perceived by caregivers
- 3 factors key: allergy to a single food, presenting with a history of anaphylaxis prior to OIT and having a low QOL before starting OIT
- Probiotic/peanut oral immunotherapy (PPOIT) trials showed benefit on psychosocial impact of food allergy and QOL especially associated with achieving sustained unresponsiveness*

*Dunn-Galvin et al. European J Allergy Immunol Oct 2017

OIT PROs

- FA affects patients' Quality of Life
- OIT reduces the risk of serious adverse reactions
- OIT improves freedom in social life
- Some studies show Quality of Life improvement during and after OIT

QUALITY of LIFE

OIT CONs

- Lack of standardized patient-related outcomes
- The burden of treatment is rarely assessed
- Lack of parental- and children-reported Quality of Life
- Discrepancies between parental and children reports

Community Private Practice Clinical Experience with Peanut Oral Immunotherapy

Yuliya Afinogenova, MD , Tamar N. Rubin, MD , Sagar D. Patel, BS , Rachel L. Powell, RN , Janina M. Gilo, APRN , Morgan N. Denno, APRN , Gary Soffer, MD , Jason O. Lee, MD, Louis M. Mendelson, MD,† , and Jeffrey M. Factor, MD

New Haven and West Hartford, Conn; and Palm Beach Gardens, Fla

J Allergy Clin Immunol Pract 2020;8:2727-35

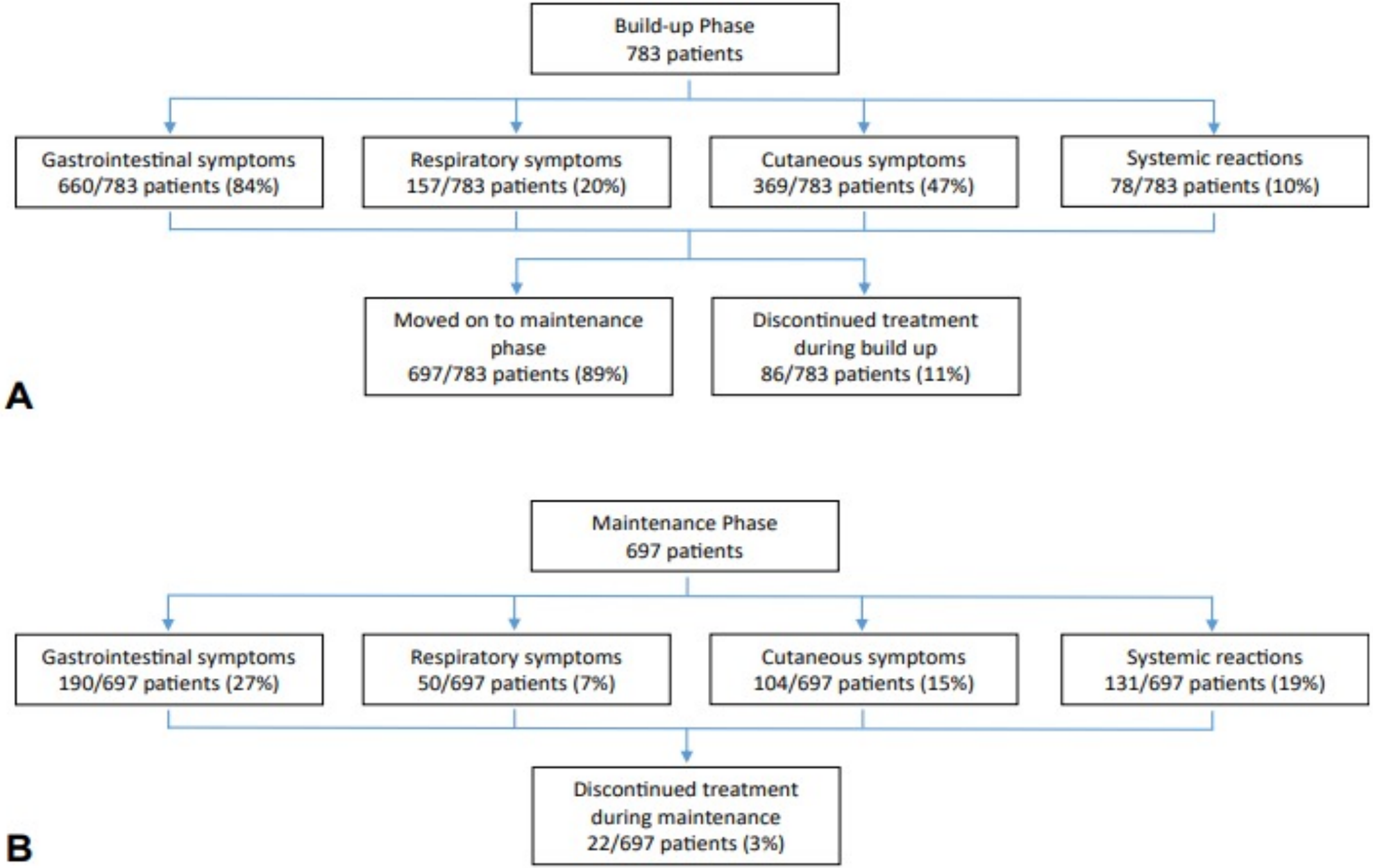
Build-up Phase
783 patients
Gastrointestinal symptoms
660/783 patients (84%)
Respiratory symptoms
157/783 patients (20%)
Cutaneous symptoms
369/783 patients (47%)
Systemic reactions
78/783 patients (10%)
Moved on to maintenance phase
697/783 patients (89%)
Discontinued treatment during build up
86/783 patients (11%)
A
Maintenance Phase
697 patients
Gastrointestinal symptoms
190/697 patients (27%)
Respiratory symptoms
50/697 patients (7%)
Cutaneous symptoms
104/697 patients (15%)
Systemic reactions
131/697 patients (19%)
Discontinued treatment during maintenance
22/697 patients (3%)
B

TABLE V. Multivariable regressions for systemic reactions in build-up and maintenance phases

Parameter	n (%)	Univariable OR (95% CI)	*P* value	Multivariable OR (95% CI)	*P* value
Systemic reactions during the build-up phase					
Age (per increase in 1 SD of age)	—	1.23 (1.00-1.51)	.05	1.20 (0.93-1.53)	.16
Sex (male vs female)	Male 45 (9.3%) Female 33 (11.1%)	0.82 (0.51-1.3)	.42	0.85 (0.51-1.45)	.56
Pre-OIT peanut IgE (per increase in 1 SD of pre-OIT peanut IgE)	—	1.66 (1.27-2.16)	<.0001	1.65 (1.24-2.20)	.001
Has patient required epinephrine for peanut allergy before OIT (yes vs no)	Yes 24 (13.1) No 52 (9.4)	1.45 (0.87-2.43)	.16	1.05 (0.58-1.91)	.88
Presence of eczema (yes vs no)	Yes 29 (8.9) No 49 (10.7)	0.82 (0.51-1.33)	.41	0.93 (0.54-1.59)	.78
Presence of asthma (yes vs no)	Yes 43 (10.4) No 34 (9.2)	1.15 (0.71-1.84)	.58	0.85 (0.51-1.45)	.56
Duration of buildup (per increase in 1 SD of duration of buildup)	—			1.32 (1.05-1.65)	.016
Systemic reactions during the maintenance phase					
Age (per increase in 1 SD of age)	—	1.28 (1.07-1.54)	.007	1.24 (1.01-1.54)	.04
Sex (male vs female)	Male 70 (16.2) Female 61 (22.9)	0.65 (0.44-0.96)	.03	0.62 (0.40-0.96)	.03
Pre-OIT IgE (per increase in 1 SD of pre-OIT IgE)	—	1.81 (1.46-2.24)	<.0001	1.64 (1.31-2.07)	<.0001
Has patient required epinephrine for peanut allergy before OIT (yes vs no)	Yes 39 (24.4) No 79 (16.2)	1.67 (1.08-2.58)	.02	1.51 (0.93-2.46)	.09
Presence of eczema (yes vs no)	Yes 49 (17.3) No 82 (19.8)	0.85 (0.57-1.25)	.41	—	—
Presence of asthma (yes vs no)	Yes 75 (20.9) No 56 (16.7)	1.32 (0.90-1.93)	.16	—	—
Presence of systemic reaction during buildup (yes vs no)	Yes 31 (34.9%) No 100 (15.9%)	4.01 (2.56-7.25)	<.0001	3.09 (1.73-5.53)	<.0001

Summary of Findings

- Elevated pre-treatment peanut specific IgE associated with heightened risk of systemic reactions during build-up and maintenance
- Increased age at start of OIT was associated with systemic reaction risk during maintenance
- Diagnosis of asthma or atopic dermatitis WAS NOT significantly associated with systemic reaction risk
- Did not assess asthma control or severity of asthma or atopic dermatitis as variables

Unmet Needs in Clinical Research

- Accepted standard definition of desensitization or another term that more accurately represents changes of clinical/immunological status
- Improved methods for measuring the impact of OIT on QOL
- Assessing OIT effectiveness and safety for patients of different socioeconomic status, race, ethnicities
- Optimal initiation doses for OIT build-up (standard or challenge-based)
- Optimal dose and duration for maintenance therapy including minimal dose necessary to maintain desensitization
- Demonstration of decrease, following OIT, in allergic reactions to foods and healthcare utilization linked to accidental exposures