375 How low can we go: preliminary efficacy of very low dose peanut oral immunotherapy

Julia Upton, MD, FRCP(C) FAAAAI[1], Duncan Lejteyni[2], Danbing Ke, PhD[3], Alireza Berenjy[4], Liane Beaudette, RN[5], Christine McCusker[6], Xiaojun Yin[4], Carmen Li[7], Lucy Duan, MD[4], Shireen Marzouk, MD, Msc, FRCPC[8], Eyal Grunebaum[9], Thomas Eiwegger, MD[10], Moshe Ben-Shoshan, MD FAAAAI[2]; [1]The Hospital for Sick Children; Division of Immunology and Allergy, University of Toronto, [2]Montreal Children's Hospital, [3]McGill University Health Center Research Institute, [4]The Hospital for Sick Children, [5]McGill, [6]Montreal Children's Hospital, [7]University of Toronto, [8]Oakville Trafalagar Memorial Hospital, [9]Hospital for Sick Children, [10]The Hospital for Sick Children; University Hospital St. Pölten.

RATIONALE: The lowest required maintenance dose of peanut oral immunotherapy (OIT) expected to provide accidental ingestion protection has not been determined. Very low dose OIT (VLOIT) may be effective.

METHODS: In an ongoing trial (49/51 enrolled, 45 randomized), peanut-allergic children reactive to </=443 peanut protein (PP) in double-blind placebo-controlled food challenges (DBPCFC) were prospectively enrolled and randomly assigned to open-label strict avoidance for 1yr (avoidance group) or to OIT to either 30mg (VLOIT group) or 300mg (300mg group) PP. OIT groups were double-blind to dose-escalation until post-escalation DBPCFC. The proportion cumulatively tolerant to >/=443 and >/=1043mg PP in the OIT groups were each compared to the avoidance group. OIT groups are planned for repeat DBPCFC 21mo post OFC initiation (primary outcome).

RESULTS: Children randomized are 51% male (95%CI 36-66), median age 10yrs (IQR 8-13), and have an initial cumulative-tolerant PP dose of 44mg (IQR 14-144). In the avoidance group, 12/15 completed 1yr DBPCFC, with 2/15 ongoing and 1/15 lost to follow-up. In the VLOIT group, 12/15 completed post-escalation DBPCFC with 1/15 ongoing and 2/15 withdrawn. In the 300mg group, 9/15 completed post-escalation DBPCFC with 3/15 ongoing and 3/15 withdrawn. No avoidance group children (0/12) tolerated >/=443 or >/=1043mg. In the VLOIT group, 10/12 (p=0.0002 vs. avoidance) tolerated >/=443 and 5/12 (p=0.04 vs. avoidance) tolerated >/=1043mg. In the 300mg group 8/9 (p=0.0002 vs. avoidance) tolerated >/=443 and 6/9 (p=0.004 vs. avoidance) tolerated >/=1043mg.

CONCLUSIONS: Current analysis shows VLOIT significantly increases the threshold of allergic reaction over strict avoidance and may allow for simplified OIT regimens.

376 Sesame Oral Desensitization Outcomes in a Pediatric Cohort

Ami Shah, MD[1], Amanda Cox, MD FAAAAI[1], Jacob Kattan, MD FAAAAI[1], Angela Tsuang, MD MSc[1], Scott Sicherer, MD FAAAAI[1], Marion Groetch, MS RDN[1], Allison Schaible, RDN[1], Roxanne Oriel, MD[1]; [1]Icahn School of Medicine at Mount Sinai.

RATIONALE: Oral desensitization is an emerging treatment option for food allergy. Limited data exists on sesame oral desensitization outcomes in the United States.

METHODS: A retrospective chart review of pediatric patients undergoing oral desensitization to sesame was conducted at a pediatric food allergy referral center.

RESULTS: Eighty-six patients with allergist-diagnosed sesame allergy (median age 5 years) underwent oral desensitization to sesame. Oral desensitization involved initial low dose oral food challenge (OFC) to crushed sesame seeds or tahini with incremental dose escalation until patients reached a maintenance dose, usually 1 teaspoon of tahini (1000mg sesame protein). Fifty-one (59.3%) achieved maintenance. Twenty-six patients (30.2%) were still in the build-up phase. Nine patients (10.5%) discontinued desensitization due to reactions (n=3), uncontrolled asthma (n=1), difficulty with daily dosing (n=1), or unknown (n=4). Twenty-five patients (29.1%) experienced allergic reactions with daily dosing with only 1 reaction requiring epinephrine. Ten patients who reached maintenance dosing also completed a full dose OFC to 1 tablespoon of tahini (3000mg sesame protein); all had negative OFCs (100%). All ten patients then underwent a sustained unresponsiveness OFC to 1 tablespoon of tahini after discontinuing daily sesame dosing for 4-6 weeks. All 10 (100%) sustained unresponsiveness OFCs were negative.

CONCLUSIONS: Oral desensitization to sesame with crushed sesame seeds and tahini can be a safe and effective way to desensitize sesame-allergic pediatric patients.

377 Variability of allergen quantity in commercially available peanut-containing foods

Justin Marsh[1], Ellenor Sell, PhD[1], Matthew Greenhawt, MD MBA MSc FAAAAI[2], Philip Johnson, PhD, BSc[3]; [1]University of Nebraska-Lincoln, [2]Children's Hospital Colorado, [3]University of Nebraska - Lincoln.

RATIONALE: Allergen-containing foods used for early introduction (EI) and oral immunotherapy (OIT) are largely uncharacterized for major allergen diversity, quantity, and batch variability. We sought to characterize peanut protein variability in quantity and consistency in foods for potential clinical therapeutic use.

METHODS: A targeted, mass spectrometry (MS)-based method using parallel reaction monitoring (PRM) was used to quantify peanut allergens Ara h 1,2,3(including isoforms),6,7,8,9,10,11 using stable-isotope labelled (SIL) peptides for absolute quantitation on a Thermo Scientific™ Q Exactive™ Plus hybrid quadrupole-Orbitrap™ mass spectrometer. Variability within and between manufacturing batches was examined. Fourteen foods were analyzed, selected through literature review of published OIT and EI literature and clinician expert opinion.

RESULTS: Allergen quantity varied across and within-product manufacturing batches in a food processing dependent manner. Heavy thermally processed foods had less detectable Ara h 1, and defatted foods less Ara h 10 and 11. Ara h 3a comprised 64-88% (weight/weight) of the allergen content by volume in the analyzed foods. Bamba had a distinct Ara h 3 isoform composition vs. the other products, and 2 EI-specific products contained more detectable Ara h 3 than other products. PB2 flour had the lowest batch allergen variability across all proteins analyzed, and Reece's pieces the highest.

CONCLUSIONS: Peanut protein quantity and distribution consistency varies among commercial products, with Bamba and PB2 flour varying the least. Allergen diversity, quantity, and variability have unclear clinical significance among foods with potential to elicit reactions, requiring further study to determine if this impacts efficacy and safety outcomes for therapeutic applications.