Allergen levels in bedroom dust samples found to be un-correlated with baseline symptoms or treatment efficacy of a novel high efficiency particulate air filtration allergen avoidance pillow (PUREZONE™)

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ABSTRACT

Introduction: Bedroom dust samples were assessed for allergen levels in a randomized clinical trial involving PUREZONE with the assumption that allergen levels would be representative of overnight subject exposures and, thus, correlate with symptom severity and treatment efficacy.

Methods: In a crossover randomized clinical trial, symptomatic adults (N=35) having perennial allergic rhinoconjunctivitis and a positive skin prick test (dust mite, dog, or cat) received PUREZONE or placebo during 2-week intervals separated by a 1-week washout. Dust samples were collected from bedding and carpeting adjacent to the bed. Allergen levels were quantified via MARIA 5-plex analysis (Indoor Biotechnologies, VA). Correlations in total symptom scores (TSS) [15-point summation of congestion, itch, sneeze, secretion, and eyes] and treatment efficacy were assessed. Approval was obtained from Western IRB and written informed consent obtained from all research subjects.

Results: Significant levels of one or more sensitizing allergens were detected in 43% of subjects' bedrooms, with significant sensitizing exposures totaling 11% for mite group 1 (>2.0 ug/g), 29% for Can f 1 (>2.0 ug/g), and 11% for Fel d 1 (>1.0 ug/g). ANCOVA models found no correlations between baseline TSS vs. sensitizing allergen exposures overnight, upon-waking, during the day, or before bed. Similar models assessing TSS reductions vs. placebo (treatment efficacy) found no correlations between treatment efficacy vs. sensitizing allergen exposures overnight or upon-waking; treatment efficacy during the day or before bed was not significant and, therefore, not assessed.

Conclusions: The results suggest that assessments of subject exposures may not be accurately represented by allergen levels found in dust samples, particularly since significant allergen levels were measured in only a low proportion of bedrooms, yet all subjects were experiencing symptoms and had no other relevant exposures than dog, cat, or dust mite. Furthermore, neither baseline symptoms nor treatment efficacy were dependent on allergen levels, yet PUREZONE was efficacious for reducing overnight symptoms ($p<0.001$). This lack of treatment efficacy correlation was unexpected given that the benefits of avoidance are normally greater for those subjects with the highest exposures.

INTRODUCTION

Allergen concentrations found in dust samples are often used to classify allergen exposures in a particular environment. In a randomized clinical trial of a personal air filtration allergen avoidance measure (PUREZONE), we sought to determine if baseline symptoms or treatment efficacy were correlated with dust sample allergen concentrations. Dust samples were collected from carpeting or bedding in accordance with NSLAH[1] methods and quantified using MARIA 5-plex[2] analysis. The complete efficacy data for the randomized clinical trial is published elsewhere[3].

PUREZONE ALLERGEN AVOIDANCE THERAPY

1 With the touch of a button, bedroom air enters the fan unit.

2 Over 99.97% of allergens and pollutants are removed through the charged-fiber HEPA filter.

3 Purified air passes through the pillowcase creating a protective, allergen-free breathing zone.

Figure 1. Active and Placebo Treatments (Active Shown Above): The active and placebo treatments were identical devices, with the exception that the placebo device delivered un-filtered air to the breathing zone.

COMPARISON OF AVOIDANCE STUDIES

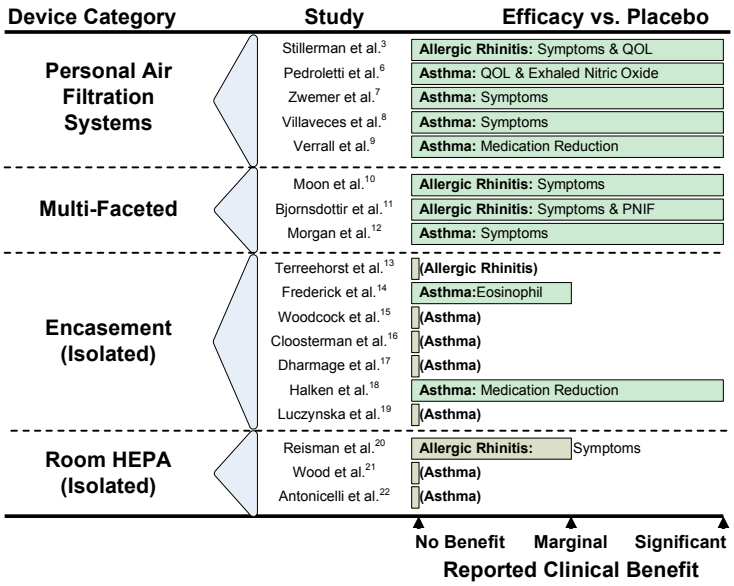

Figure 5. Review of Allergen Avoidance Measure Efficacy: Reported clinical benefits vs. placebo for a select group of studies.

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BASELINE SYMPTOMS UN-CORRELATED WITH EXPOSURE

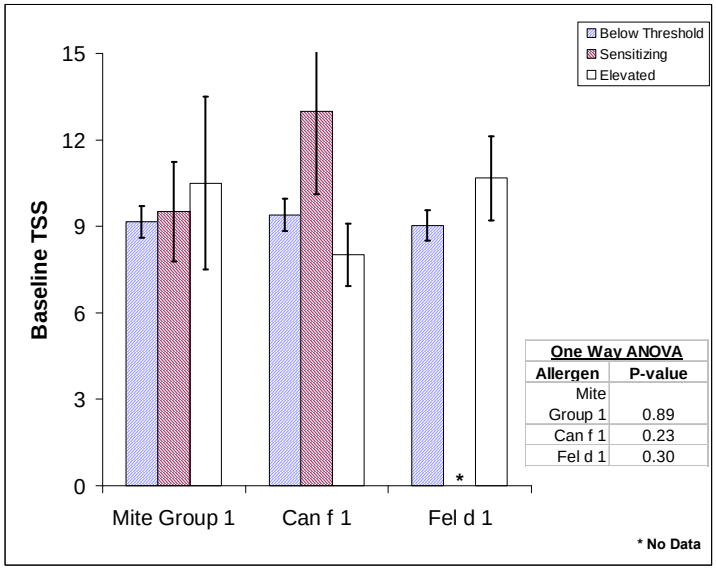

Figure 2: Mean Baseline symptoms (±SEM) for subjects by exposure classification based upon dust sample allergen concentrations (below threshold, sensitizing, elevated)[4]: (0-2,2-10,>10) ug/g for Mite group 1 and Can f 1; and (0-1,1-8,>8) ug/g for Fel d 1.

TREATMENT EFFICACY UN-CORRELATED WITH EXPOSURE

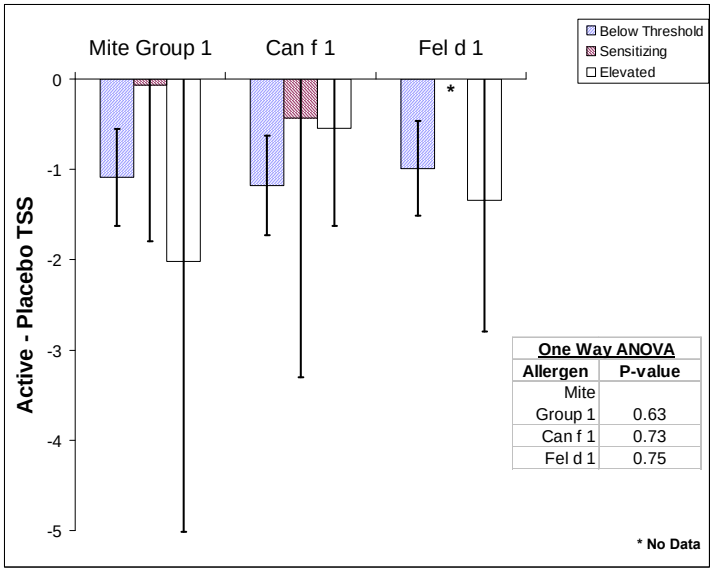

Figure 3: Symptom reductions vs placebo (±SEM) for subjects by exposure classification based upon dust sample allergen concentrations (below threshold, sensitizing, elevated)[4]: (0-2,2-10,>10) ug/g for Mite group 1 and Can f 1; and (0-1,1-8,>8) ug/g for Fel d 1.

CLINICAL BENEFITS REPORTED FOR MULTIPLE OUTCOMES VS PLACEBO

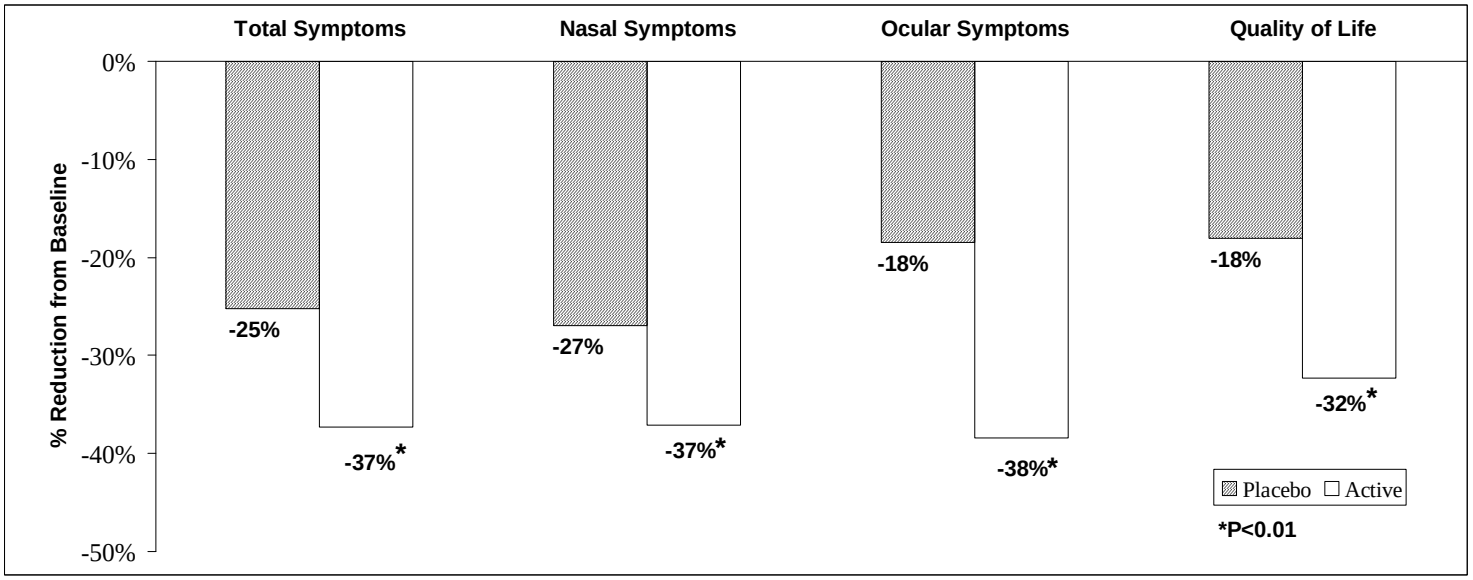

Figure 4. Symptom Reductions and Quality of Life Improvements vs. Placebo: Percent change in total (TSS), nasal (TNSS), and ocular symptoms upon waking and quality of life (NRQLQ[5] composite) from baseline.
P-values indicate the signifigance of the Active – Placebo contrast.

CONCLUSIONS

The clinical benefits of PUREZONE were consistent across the study population and unrelated to dust sample allergen concentrations. This outcome suggests the following:

- Dust sample allergen concentrations may not have been representative of the actual allergen exposures faced by subjects in their bedrooms. This is possible because many patients benefited from night-time avoidance in bedrooms having allergen exposures classified as "below the threshold for sensitization."
- Environments having allergen dust sample concentrations below the commonly accepted thresholds for sensitization[4] may still provide enough exposure to cause symptoms. This is supported by baseline symptomatology, for which all subjects having bedroom exposures "below the threshold for sensitization" reported nocturnal symptoms, yet their only relevant sensitizations were to dog, cat, or dust mite allergen.

It is difficult to contrast our findings against those of other avoidance studies because:

- Trials of other personal air filtration devices did not involve allergen dust samples.
- Trials of other stand-alone avoidance measures (encasement, room HEPA) involving allergen dust samples have generally lacked clinical benefits. Multi-faceted trials typically involve targeting multiple allergen sources with multiple interventions that extend beyond the bedroom.