Baseline Challenge Responses during Repeated, Daily Controlled Exposures to Grass Pollen in the Environmental Exposure Unit (EEU)

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Objective

To describe the pattern of symptomatic responses following four consecutive pollen exposure visits, and to determine if such a protocol enhances the ability for potential study qualification compared to a priming model.

Methods

- **Healthy males or females between the ages of 18 and 65 with a positive skin prick test to rye grass allergen and at least a two-year history of seasonal allergic rhinitis symptoms during the grass pollen season and who were non-asthmatic were eligible to participate.**
- **Participants were excluded if they had a previous history of asthma (greater than GINA step 1); a history of anaphylaxis to grass allergen; FEV1 < 80% predicted; had received immunotherapy within 12 months or had any history of grass immunotherapy within 10 years; received treatment with beta blockers; were unable to receive epi-epinephrine; or had a history of recurrent acute or chronic sinusitis and significant drug or alcohol abuse.**
- **After providing written consent, participants underwent the following procedures at screening:** vital signs, skin testing to a panel of allergens (including rye grass), height & weight, physical examination including detailed nasal examination, routine blood and urine testing (including pregnancy testing for women of childbearing potential) and spirometry.

Results

- A total of 348 participants were screened, of which 214 were eligible and attended all 3 of the 3 x 3 hour EEU visits. Mean TRSS and TNSS scores amongst participants after the first 3 hour exposure were 13 and 7, respectively. In the conclusion of Day 2, these values were 15 and 8; following Day 3 they were 17 and 8. 17 participants did not meet the required TRSS/TNSS scores on Day 3 and were excluded at that point. Final mean TRSS and TNSS concluding Day 4 were 18 and 9; one participant did not re-qualify on Day 4.

Discussion

- **The EEU has been in operation since the late 1980’s and is currently distributed ragweed pollen due to the high local prevalence of ragweed allergy (Day and Bisaccio, Ann Allergy Asthma Immunol 1999; 83: 82-87).**
- We have validated the dispersal equipment for the distribution of grass pollen (Byrnes and Ellis, Ann Allergy Asthma Immunol 2011; 107(1): 40) and the allergic rhinitis responses of grass allergic individuals (Titus et al, Ann Allergy Asthma Immunol 2010; 104: 293-4).
- The current study suggests that the traditional priming design would be the preferable method as it allows the sessions to adapt to the individual needs of the participants instead of the group as a whole. With a priming session, the high responders can leave the EEU upon achieving the required symptoms to prevent unnecessary exacerbation of their allergy symptoms.

Conclusions

- High responders are able to maintain their qualifying symptoms suggesting that repeated pollen exposure visits after the participants qualify are unnecessary.
- Low responders do appear to require multiple days to qualify but once they reach the required level of symptoms they are reproducible each subsequent day.
- Participants who exhibit little to no symptoms on Day 1 are unlikely to qualify scoring after repeated exposure sessions.