Introduction

Allergen challenge chambers expose allergen-sensitive subjects to a predetermined concentration of allergen in a closed, controlled environment and provide a mechanism to induce clinical symptoms and measure the effect of medication. The purpose of this study was to validate the Red Maple Trials ACT (Allergen Challenge Theatre) for controlled grass pollen inhalation studies. First, the ACT underwent a technical validation to ensure that grass pollen concentrations were stable over several hours and uniform throughout the ACT. Second, symptoms were evaluated in grass-allergic subjects exposed to a constant pollen concentration on 2 separate days to ensure reproducibility of the response.

Methods

Grass pollen was aerosolized in the ACT and concentrations were measured using an array of impact samplers and a laser particle counter which controlled the dispersion of the pollen. The relationship between laser particle counter and impact sampler readings was evaluated over a range of grass pollen concentrations. The stability of ragweed concentration was evaluated over a 3-hour period at a constant pollen output.

The study population consisted of healthy male and female adults 18 to 65 years of age with a clinical diagnosis of seasonal allergic rhinitis, positive skin prick tests to grass pollen and nasal symptoms during the grass pollen season in the previous 2 years. Each subject gave written informed consent before participation in any study evaluations were performed. Thirty-one eligible subjects were recruited and were exposed to Timothy grass pollen (Phleum pratense) for 3 hours on two separate days. One subject dropped out after the first challenge leaving an evaluable population of 30 subjects. Total nasal (TNSS), ocular (TOSS) and total respiratory symptom scores (TRES) were recorded at baseline and every 30 minutes during each challenge. Pollen concentrations were also measured every 30 minutes during the challenge.

Results

For the clinical validation, the mean pollen concentration was 3359 grains/m³ for Challenge 1 and 3468 grains/m³ for Challenge 2. At the first challenge, responses ranged from no symptoms to a maximum TNSS of 9 as be expected in a population of unprimed subjects. At the second challenge, symptom scores were higher over the last hour of exposure and were significantly different at 180 min (Table 2 and Figure 1). However, AUC which reflects the whole exposure was not significantly higher (Table 1).

Conclusion

This study demonstrated that the Red Maple Trials ACT can generate constant and reproducible grass pollen concentrations and consistent symptoms in response to allergen challenge in primed subjects. Unprimed subjects have increased symptoms with subsequent challenges as has been demonstrated previously.

References

• Bernstein, J.A., ed. Correlation between a pollen challenge chamber and a natural allergen exposure study design for eliciting ocular and nasal symptoms: Early evidence supporting a paradigm shift in drug investigation? Journal of Allergy and Clinical Immunology. 2012; 130: 128-129.
