

The Controlled Allergen Challenge Experience: Comparison of Allergic Upper Respiratory Symptoms in the Environmental Exposure Unit (EEU) and During Seasonal Exposure



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Introduction

A randomized controlled trial over 2-4 weeks in season is the basis for determining medication efficacy in seasonal allergic rhinitis (SAR). An additional study method employs single-dose responses using controlled allergen challenge exposure units, such as the Environmental Exposure Unit (EEU). Different allergen challenge models have been used in several centers across North America and Europe to establish onset of action as well as other efficacy measures of various anti-allergic treatments.

Although subjects participating in EEU trials report similar symptomatology to that experienced during pollen season, a rigorous comparison of allergic symptoms generated by controlled allergen challenge with those occurring in season has not been reported.

Objective

This study was designed to document and directly compare the actual nature and severity of symptoms experienced by subjects during natural exposure to pollen in ragweed season, to those experienced during controlled ragweed challenge in the EEU.

Methods

Surveys:

A survey to document nature and severity of SAR symptoms in ragweed season, and a second survey to document nature and severity of SAR symptoms while in the EEU with identical scales and wording were developed in consultation with Dr. R. Holden, Dept of Psychology, Queen's University. Severity of symptoms were rated on a 10 point scale (from 0 = No Symptoms to 9 = Worst Symptoms Imaginable).

During the third week of ragweed season (mid-September 2003), the survey was mailed to 1821 subjects on file who had documented ragweed allergy and had either participated in at least one EEU clinical trial or had agreed to be contacted for future research opportunities.

The EEU survey was provided to all subjects participating in an EEU clinical trial from October to December 2003.

Statistical Analysis:

Both an "All respondents" and a "Common respondents" comparison were completed:

- » Nominal data were compared using Chi-Square
- » Continuous data were compared using Mann-Whitney Test for non-parametric data

Results

- 550 of the 1821 subjects completed and returned the ragweed season (RWS) survey, for a response rate of 30%
- 516 subjects completed the EEU survey (78%)
- 270 subjects completed both

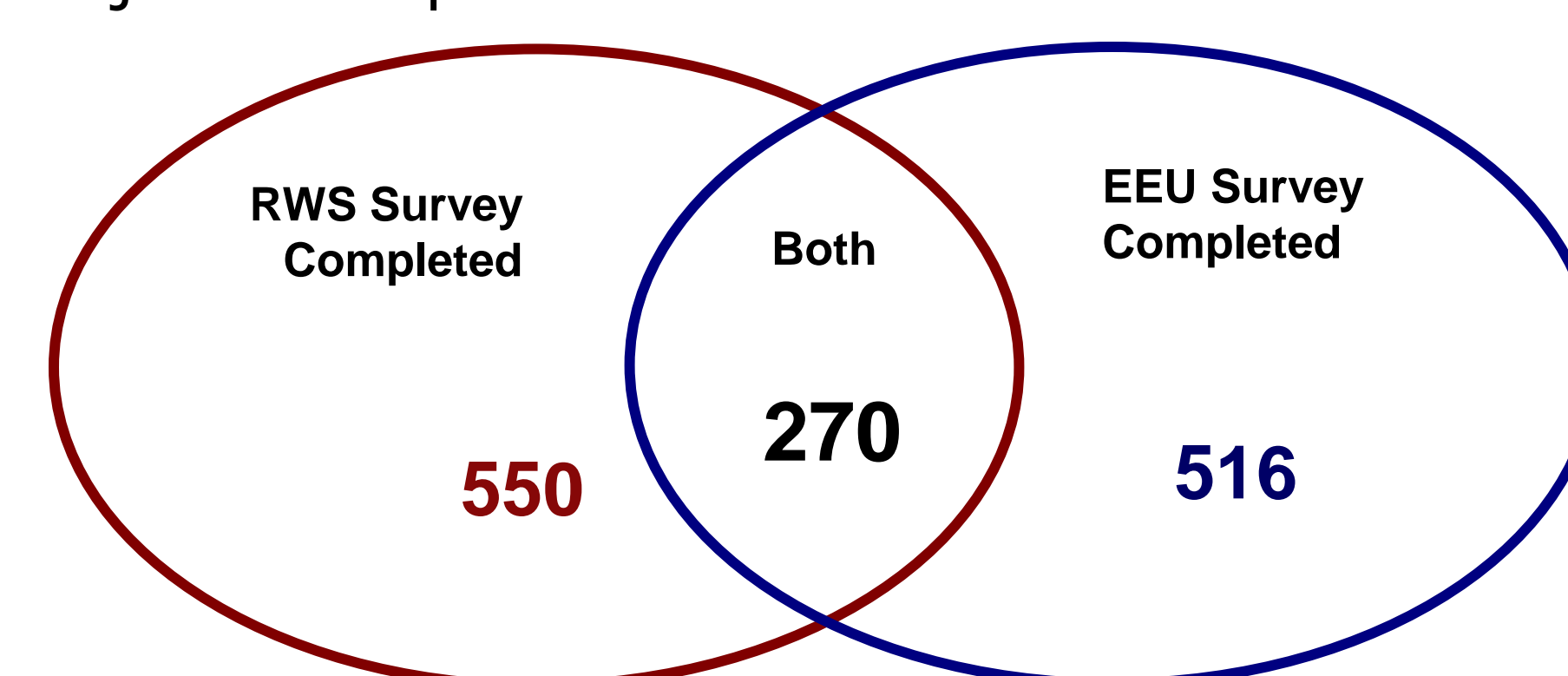
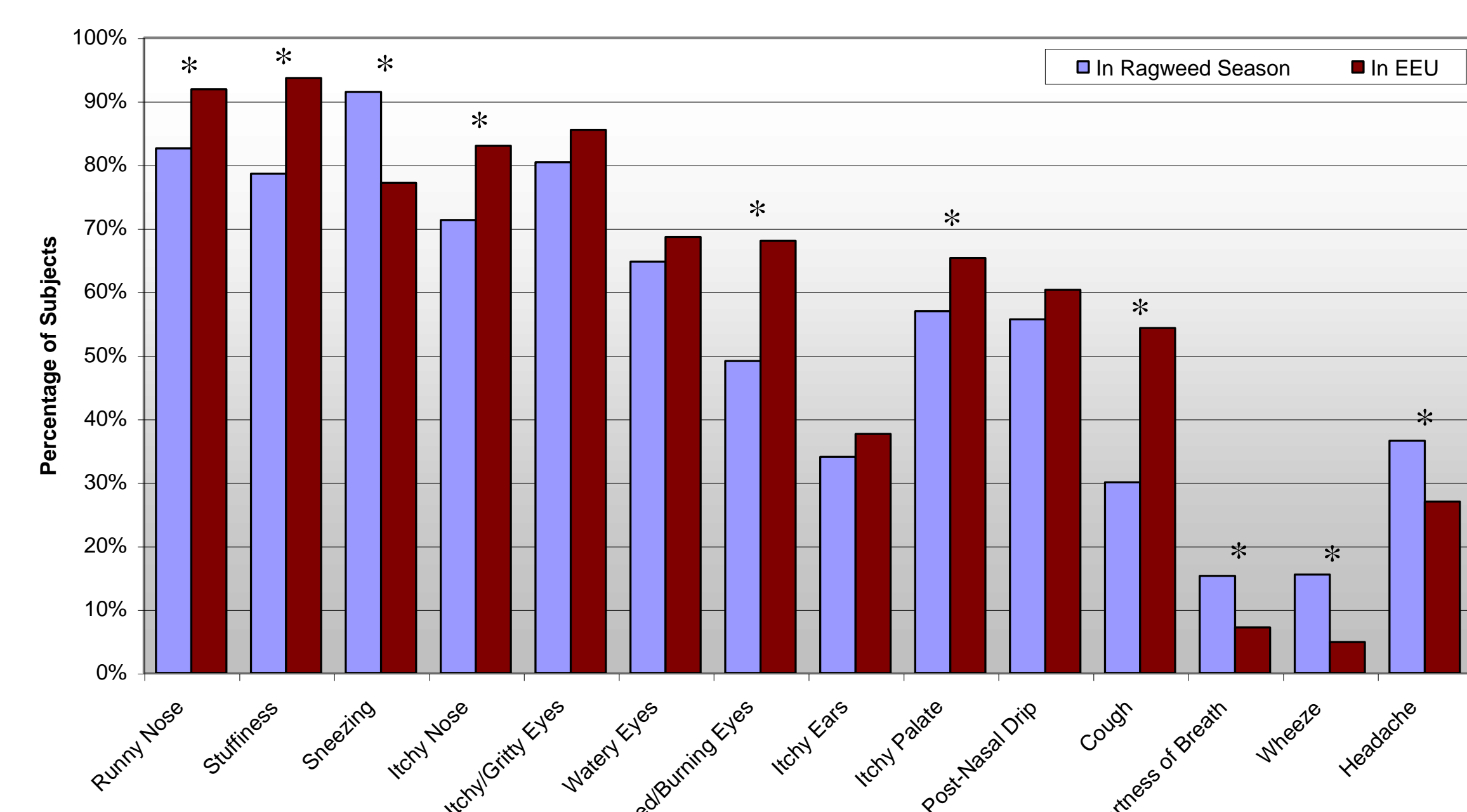
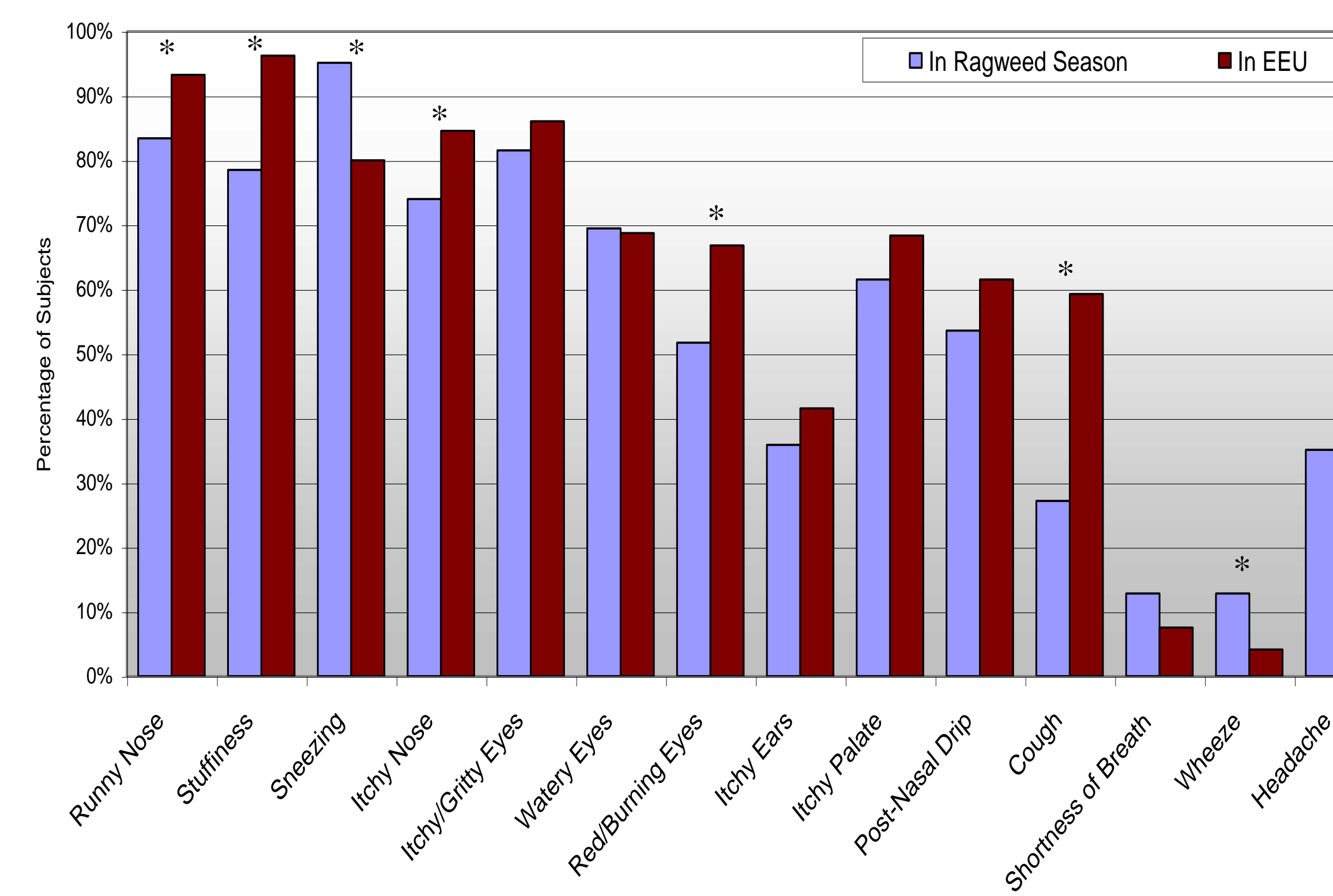


Figure 1: Frequency of Reported Symptoms; All respondents



*difference between groups, $p < 0.05$

Figure 2: Frequency of Reported Symptoms; Common Respondents

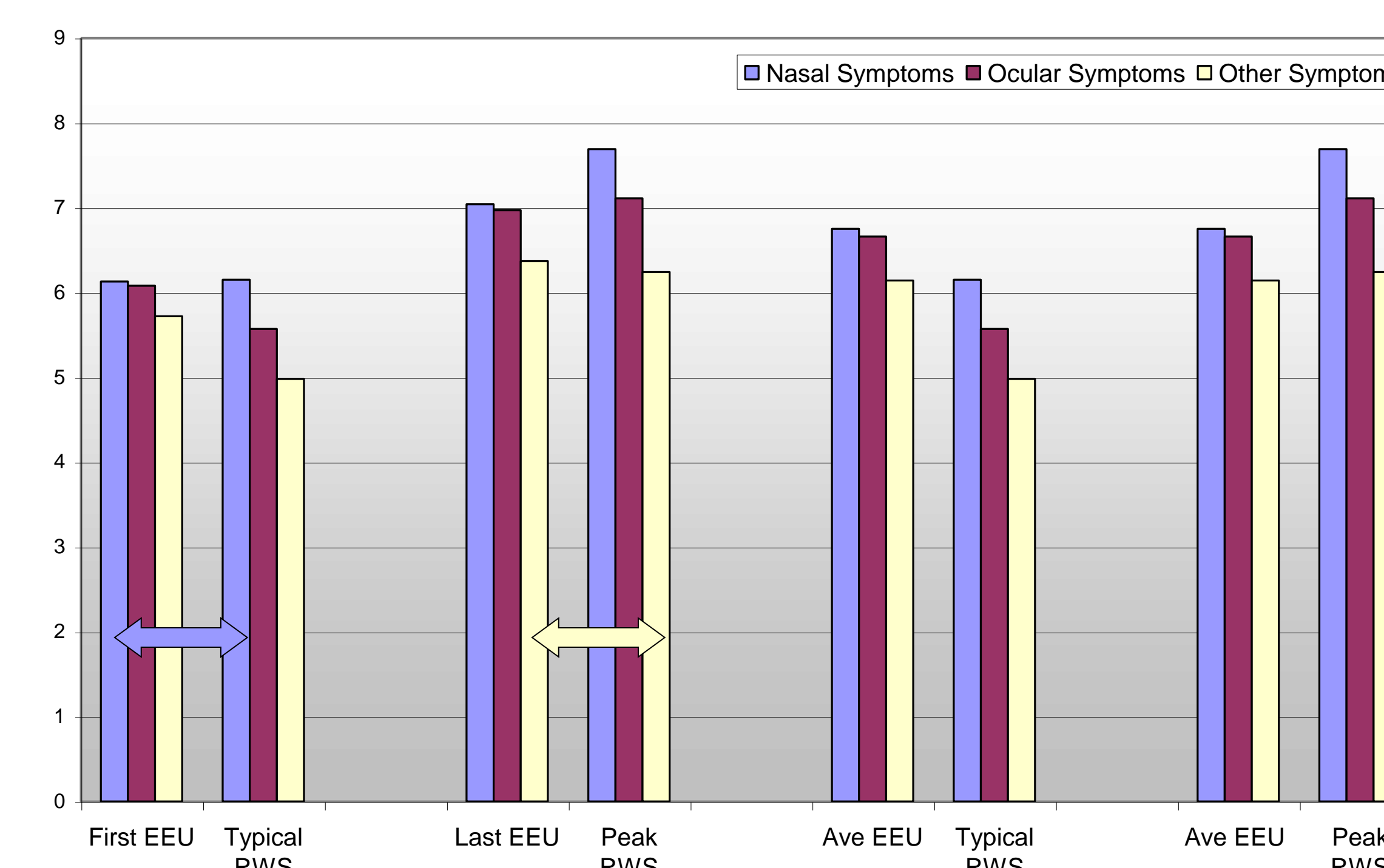


*difference between groups, $p < 0.05$

Results - continued

Symptoms generated by the EEU were more severe than those experienced on a *typical* ragweed season day, but less severe than those on *peak* days during the season

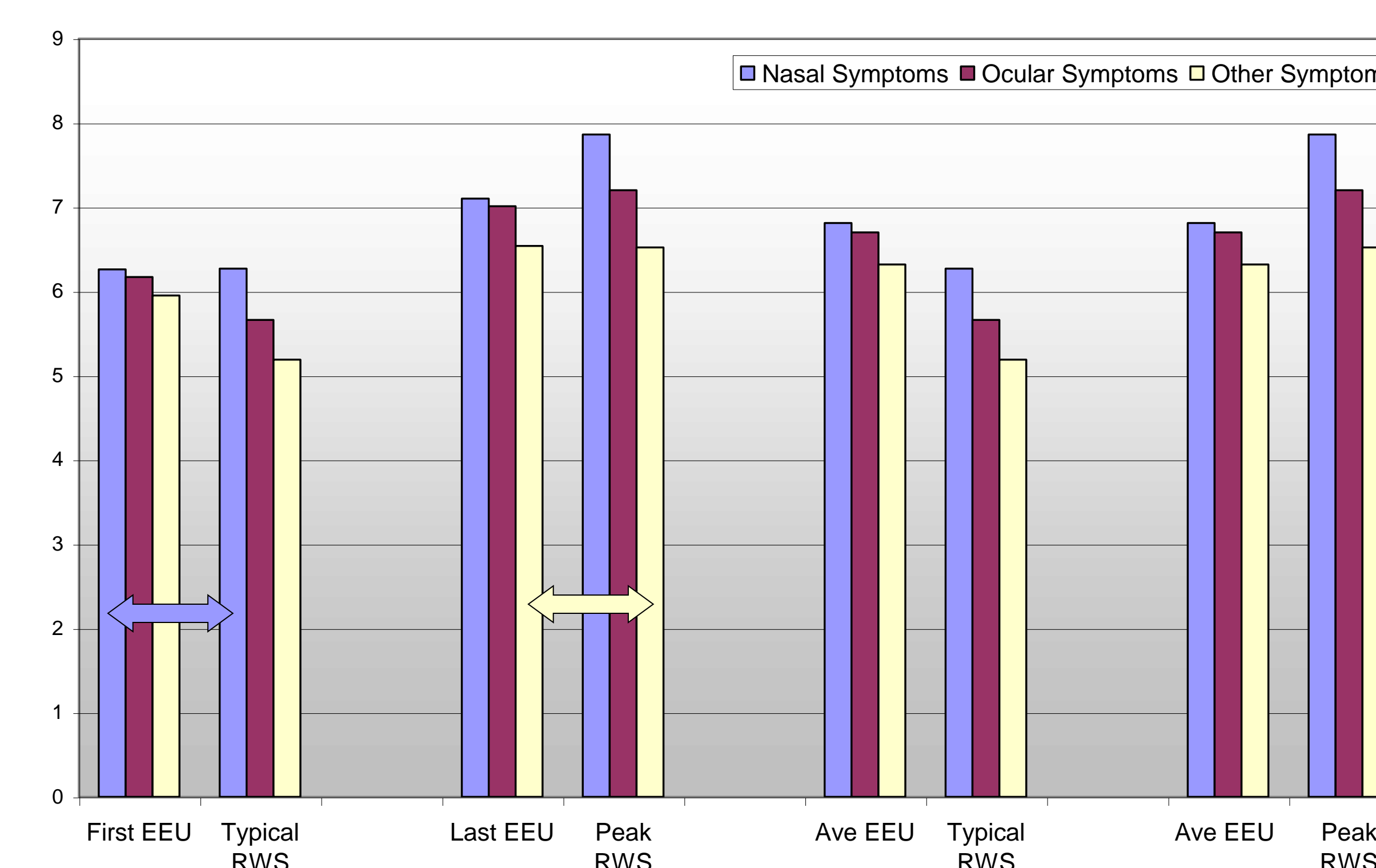
Figure 3: Severity of Symptoms; All respondents



First EEU = Symptoms from first priming exposure
Last EEU = Symptoms from last priming exposure
Ave EEU = Symptoms from average priming exposure

↔ = no significant difference

Figure 4: Severity of Symptoms; Common respondents

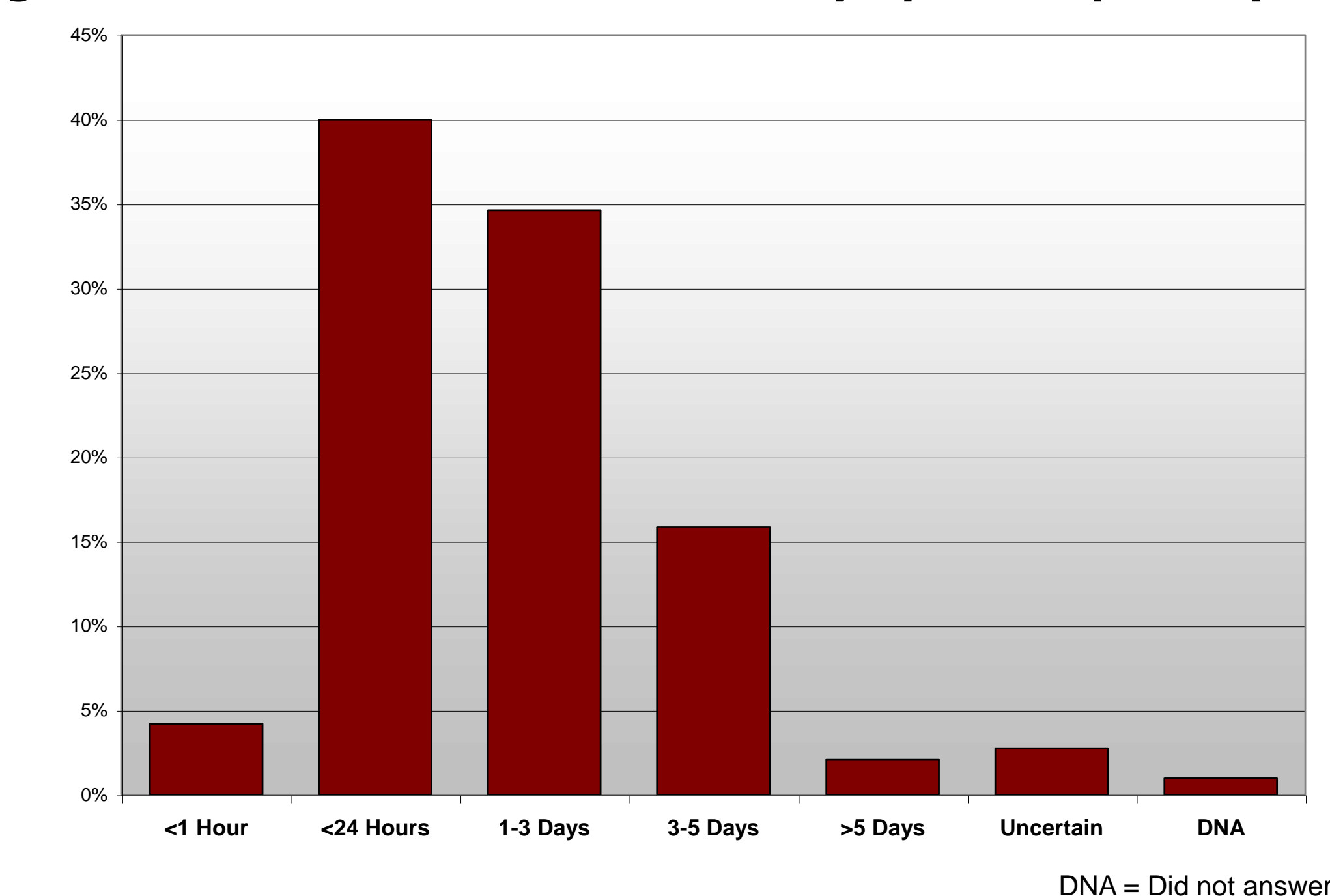


First EEU = Symptoms from first priming exposure
Last EEU = Symptoms from last priming exposure
Ave EEU = Symptoms from average priming exposure

↔ = no significant difference

Results - continued

Figure 5: Time to resolution of SAR Symptoms upon departing EEU



Discussion

Symptoms experienced by subjects with SAR in ragweed season were comparable to those generated by the EEU, with notable exceptions being a higher frequency of red/burning eyes, and cough in the EEU.

A sub-analysis of those subjects reporting cough revealed that they were significantly more likely to have reported a history of asthma. The reasons for an increased report of eye symptoms are unclear.

Frequency differences in nasal symptoms such as runny nose and stuffiness, while statistically significant, were less than 10% and thus not likely clinically significant.

The severity of symptoms generated by the EEU were slightly more severe (*i.e.* one severity point on scale of 0 to 9) than those experienced on an average ragweed season day, but less severe than those on peak days.

Over 75% of subjects noted full resolution of symptoms within 3 days of the EEU exposure.

Conclusions

- **SAR symptoms produced by controlled ragweed allergen challenge in the EEU are comparable to those induced by natural exposure in ragweed season, the exceptions being increased cough and red/burning eye symptoms.**
- **Symptom severity with EEU exposure lies between typical and peak natural pollen exposure.**
- **The overall comparability of symptoms is evidence that the EEU is a valid model for the study of SAR.**