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Clinical evaluation of an allergen Challenge Theatre™

Jacob Karsh*, Suzanne Kelly, Jimmy Yang, Rob Perrins, William H Yang

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Background

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.

Methods

A preliminary evaluation of the capabilities of the newly constructed Red Maple Trials Allergen Challenge Theatre™ was performed. Health Canada and a provincial Ethics Board approved the study. After signing informed consent, patients with a history of grass allergy, not on allergy medications and with a positive skin prick test to grass antigen (≥ 3 mm) were exposed for 3 hours to timothy grass pollen (*Phleum pratense*) in the allergen challenge theatre. Total nasal (TNSS) and rhinoconjunctivitis symptom scores (TRSS) were recorded at baseline and every 30 minutes during the challenge.

Results

32/50 patients evaluated demonstrated a positive skin prick test and were challenged. Baseline TNSS and TRSS (Mean± SD) were 0.6±1.04 and 0.6±1.07 respectively. Symptom scores reached a plateau at 30 minutes (TNSS 4.8±2.68; TRSS 5.8±3.69) and remained steady for the 180-minute exposure period reaching final values of TNSS 3.7±2.16; and TRSS 5.8±3.79. Because entry to a therapeutic trial usually requires achieving a TNSS ±5 during a priming exposure, we calculated the results for the 17/32 patients reaching this score at 30 minutes (TNSS 6.65±2.21; TRSS 8.35±3.18). Scores held steady and at 180 minutes were: TNSS 4.71±1.69; TRSS 7.88±3.06. No unexpected adverse events were reported during the challenge.

Conclusions

The Red Maple Trials allergen exposure theatre demonstrated the capacity to induce symptoms of appropriate intensity upon allergen challenge. The chamber with a seating capacity of 99 places has the ability to evaluate large test groups at a time.

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Red Maple Trials Inc., Ottawa, Ontario, Canada