Symptom Relief and Improved Quality of Life in Allergic Rhinitis Patients After Transdermal Allergy Immunotherapy

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Introduction

Patients with allergic rhinitis (AR) experience side effects from pharmacotherapies and subcutaneous immunotherapy (SCIT). Altering the mode of antigen delivery by mixing allergens with topical formulations may prove to be beneficial in treating AR in patients who have tried or failed SCIT and may confer substantially less side effects when compared to systemic medications. This ongoing, prospective, observational study (IRB-approved, informed consent) is titled Transdermal Relief: Evaluating Allergy Topicals for Seasonal and Perennial Allergic Rhinitis (the TREAT study). It assesses changes in Mini Rhinoconjunctivitis Quality of Life Questionnaire (MiniRQLQ®, self-administered) scores and symptoms from baseline to 3 months for patients with AR using a transdermal allergy immunotherapy (TdIT) formulation.

Methods

- In this observational study, patients 12-64 years old with seasonal/perennial AR who tried/failed SCIT, applied a TdIT with selected allergens compounded in a transdermal base cream over three months.
- Patients completed a survey at baseline, ~1.5 months and ~3 months to assess symptoms, quality of life, satisfaction and side effects.
- Paired data were collected between January 2016 and November 2017 from eight physicians' practices across six US states (Iowa, Georgia, Ohio, Florida, Texas, and Missouri).
- Investigators' specialties were: allergy (3), otolaryngology (2), and general medicine, podiatry and orthopedics (each 1).
- This interim analysis compares baseline to 3-month results.
- Statistically significant differences were calculated using the McNemar test for binomial data and the Wilcoxon test (data were not normally distributed) for scale data. Alpha was set at .05.

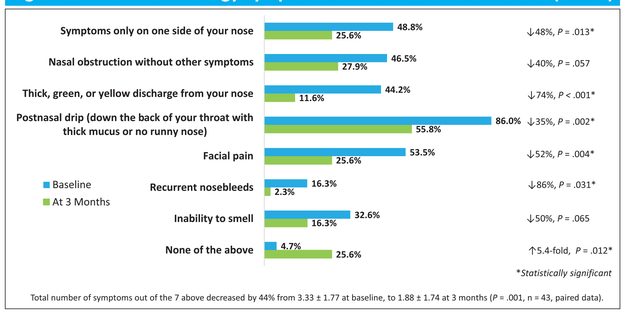
Results

Table 1. Patient Characteristics (n = 43)

	Mean ± SD	Range
Female/Male (n)	30 / 13	
Age at Baseline (years)	43.4 ± 14.6	12.1 - 63.6
How long had allergy symptoms (n)	< 1 year: 1 1-5 years: 11 > 5 years: 28 Not specified: 3	
Age when symptoms first appeared (years)	22.8 ± 16.8	6 - 65
Days between Baseline and 3-Month Survey	93.9 ± 32.8	52 - 183

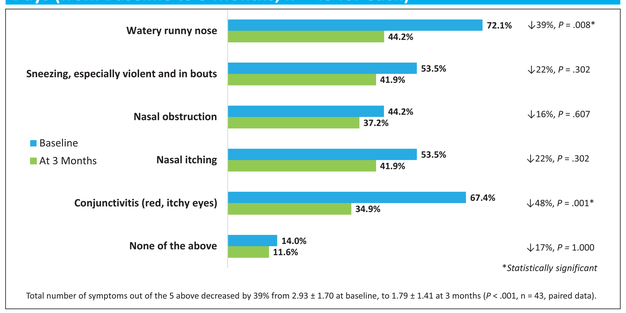
SD = standard deviation

Figure 1. Decrease in Allergy Symptoms from Baseline to 3 Months (n = 43)



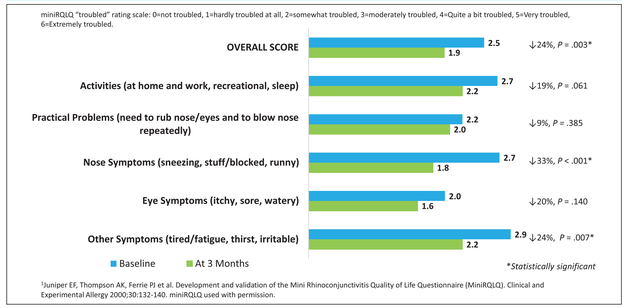
Total number of symptoms out of the 7 above decreased by 44% from 3.33 ± 1.77 at baseline, to 1.88 ± 1.74 at 3 months (P = .001, n = 43, paired data).

Figure 2. Decrease in Allergy Symptoms Lasting at Least 1 Hour on Most Days (from Baseline to 3 Months, n = 43 for each)



Total number of symptoms out of the 5 above decreased by 39% from 2.93 ± 1.70 at baseline, to 1.79 ± 1.41 at 3 months (P < .001, n = 43, paired data).

Figure 3. Decrease in miniRQLQ[1] Scores Overall and for Each of 5 Components from Baseline to 3 Months (n = 43 for each)



[1]Juniper EF, Thompson AK, Ferrie PJ et al. Development and validation of the Mini Rhinoconjunctivitis Quality of Life Questionnaire (MiniRQLQ). Clinical and Experimental Allergy 2000;30:132-140. miniRQLQ used with permission.

Figure 4. Patient Experience at 3 Months (n = 43 for each)

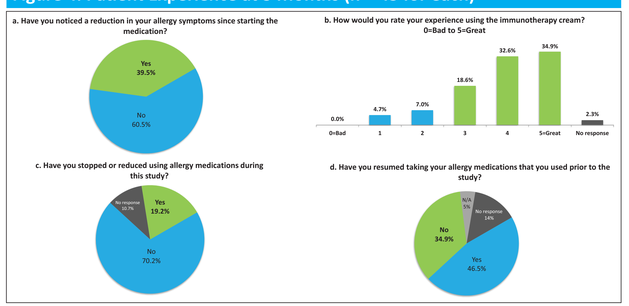


Table 2. Patient-reported Side Effects from Transdermal Allergy Immunotherapy* (n = 43)

Side Effect	At 3 Months n, %
None	34, 79.1
Yes	9, 20.9
Rash redness	3
Rash or redness (only once or twice)	1
Slight itching at application	1
Other (unspecified)	2
Not specified	2

*No serious AEs were reported.

Conclusions

- Interim results from the TREAT study demonstrated that patients with AR receiving TdIT for 3 months had:
  - improved quality of life as measured by the miniRQLQ;
  - reduced AR symptoms;
  - a positive experience with the treatment;
  - minimal side effects;
  - reduction in other allergy medication use.
- These interim results provide promise that topical administration of allergens may be a potential alternative to SCIT or SLIT immunotherapy.
- The results are also aligned with those of a study using the same formulation on mouse skin, which found a dose-dependent decrease in IgE and a trend for increased IgG2 levels with increased doses.[1]

Limitations

This is an observational survey study. Changes observed cannot definitively be attributed to the TdIT treatments. Further study is therefore required.

References

1. Plunkett G. et. al., Effects of *In Vivo* Treatment on Anti-OVA Antibody Production in Mice, Poster # 222, AAAAI Annual Meeting, March 2-5, 2018, Orlando, Florida, USA.

Disclosure

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