Ann Allergy Asthma Immunol 120 (2018) 53–58

Contents lists available at ScienceDirect

Efficacy and safety of birch pollen immunotherapy for local allergic rhinitis

Andrzej Bożek, MD, PhD [*]; Krzysztof Kołodziejczyk, MD, PhD [†]; Jerzy Jarząb, MD, PhD [*]

[*] Clinical Department of Internal Disease, Dermatology and Allergology in Zabrze, Medical University of Silesia, Katowice, Poland
[†] Allergy Outpatient Clinic, Katowice, Poland

ARTICLE INFO

Article history:
Received for publication September 12, 2017.
Received in revised form September 29, 2017.
Accepted for publication October 4, 2017.

ABSTRACT

Background: Local allergic rhinitis (LAR) is a relatively new disease.
Objective: To ascertain the effects of allergen-specific immunotherapy in LAR.
Methods: A randomized, double-blind, placebo-controlled trial of birch subcutaneous allergen immunotherapy (AIT) for LAR was performed in 28 patients. The therapy was performed for 24 months in 15 patients with AIT and 13 patients given placebo. The primary end point was decrease in symptom medication score (SMS). In addition, we monitored serum-specific immunoglobulin E (IgE), serum-specific immunoglobulin G4, nasal-specific IgE to Bet v 1, and safety and quality-of-life parameters.
Results: After 24 months of treatment, there was a significant decrease in the median area under the curve for SMS of the active group vs the placebo group: 2.14 (range, 1.22–4.51) vs 6.21 (range, 5.12–7.89), at the $P < .05$ level. During AIT, the active group showed a significant decrease in SMS of up to 65% vs baseline. A significant increase in immunoglobulin G4 and decrease in nasal-specific IgE were observed in the active group during AIT compared with the placebo group. AIT was well-tolerated and without systemic reactions.
Conclusion: This study demonstrates that AIT for birch pollen in patients with LAR was clinically effective and exhibited good tolerance.
Trial Registration: ClinicalTrials.gov Identifier: NCT03157505.
© 2017 American College of Allergy, Asthma & Immunology. Published by Elsevier Inc. All rights reserved.

Introduction

Local allergic rhinitis (LAR) is an underdiagnosed and undertreated disease characterized by the local production of immunoglobulin E (IgE) during natural exposure to aeroallergens. Patients with LAR have negative skin prick and serum-specific IgE test results but positive nasal provocation test (NPT) results for aeroallergens.[1,2] More than 50% of patients with chronic nonallergic rhinitis may have problems due to the lack of an LAR diagnosis,[2,3] because a misdiagnosis can lead to treatment inefficiency and errors.

In addition to the local IgE-mediated reaction, allergen immunotherapy (AIT) is a potential treatment method for these patients. However, sufficient data are only available to show that AIT is effective in allergic rhinoconjunctivitis and asthma in response to pollens, house dust mites, and some animals.[4,5]

The aim of our study was to assess the safety and efficacy of AIT for birch pollen allergens in patients with LAR and a confirmed birch pollen allergy.

Methods

This study was a double-blind, placebo-controlled, randomized trial conducted at a single center. All patients participating signed an informed consent form. The study was approved by the local ethics committees of the Medical University of Silesia (34211/2014).

Patients

First, we screened 78 patients (43 women and 35 men; age range, 18–76 years) from a group of approximately 1,560 subjects with suspicion of inhalant allergies and suspicion of LAR. The number of screened participants received was based on a power calculation that took into account the expected effect size. The following formula was used to compare the 2 proportions: $N = 16p(1 - p) / (p0 - p1)^2$ and $p = (p0 + p1)$, for $p = 0$ and $p1 = 0.1$. All patients were recruited from January 2014 to February 2014 at one allergy outpatient center in southern Poland. Next, the screened patients were checked based on the following criteria:

1. Well-documented symptoms of rhinitis during birch pollen season.
2. A positive NPT to birch.
3. Negative skin prick test results for inhalant allergens, including *Dermatophagoides pteronyssinus*, *D farinae*, grass pollen, birch, hazel, alder, *Alternaria*, and cats.

Reprints: Andrzej Bożek, MD, PhD, Clinical Department of Internal Disease, Dermatology and Allergology, Medical University of Silesia, MC Sklodowskiej 10, Zabrze 41-800, Poland; E-mail: andrzejbozek@o2.pl.
Disclosures: Authors have nothing to disclose.

https://doi.org/10.1016/j.anai.2017.10.009
1081-1206/© 2017 American College of Allergy, Asthma & Immunology. Published by Elsevier Inc. All rights reserved.

Table 1
Summary of Patients' Characteristics Before Randomization

	Active	Placebo	*P* value
Randomized patients (n)	16	13	.68
Age (y)	22.7 ± 3.1	24.9 ± 4.2	.87
Female (%)	8 (50)	6 (46)	.83
Duration of rhinitis (y)	5.3 ± 2.7	6.1 ± 3.9	.63
Mean weekly symptoms score in basement during birch pollen season	4.64 ± 1.54	4.32 ± 1.95	.49
Total serum IgE	62.81 ± 22.17	56.19 ± 17.65	.33
Specific nasal serum IgE to birch pollen in nasal lavage (kU/L) after NPT	1.89 ± 0.39	1.62 ± 0.84	.78
Mean symptom score after NPT to birch pollen	5.54 ± 2.11	5.38 ± 2.44	.72
Mean nasal flow decrease after NPT to birch pollen (%)	79.2	82.5	.33

Abbreviations: IgE, immunoglobulin E; NPT, nasal provocation test.

4. Negative serum total and allergen-specific IgE results against the aforementioned allergens.
5. Lack of diagnoses of bronchial asthma, nonallergic rhinitis (especially senile or vasomotor rhinitis), and severe, nonstable diseases.

Twenty-nine patients who fulfilled all criteria, ranging from 21 to 68 years of age, were included in the study. The subjects had moderate or severe intermittent allergic rhinitis during birch pollen season (March–May) in Poland and fulfilled the Allergic Rhinitis and its Impact on Asthma (ARIA) criteria.[6] Randomization Procedure and Blinding.

After the expected dropout period, 29 participants were randomized to 2 treatment groups at a 1:1 ratio. The randomization procedure with random selection relied on the use of computer-generated numbers via a flip-coin generator (Excel, version 14.2.0, 2011, Microsoft Corp, Redmond, WA). The patients were allocated to 2 groups: an AIT group for the administration of perennial AIT with Purethal Birch (HAL Allergy BV, Leiden, The Netherlands) and a placebo group for administration of subcutaneous placebo injections for 24 months.

Finally, 15 subjects in the AIT group and 13 subjects in the placebo group completed the 24-month observation period. The groups had comparable characteristics at baseline (Table 1). A diagram of the enrollment protocol is presented in Figure 1.

For study-blinding purposes, all patients received the same volume and same number of injections. The investigator, subjects, and personnel remained study-blind throughout the investigation until the database was locked.

The placebo was a sterile aluminum hydroxide suspension packed in bottle similar to that of the active drug and packed in the same type of unidentified white boxes with only the identification number of the patient and key number of the drug. All key codes to identify the active drug or placebo were locked by an independent coordinator who did not participate in the study until the study finished.

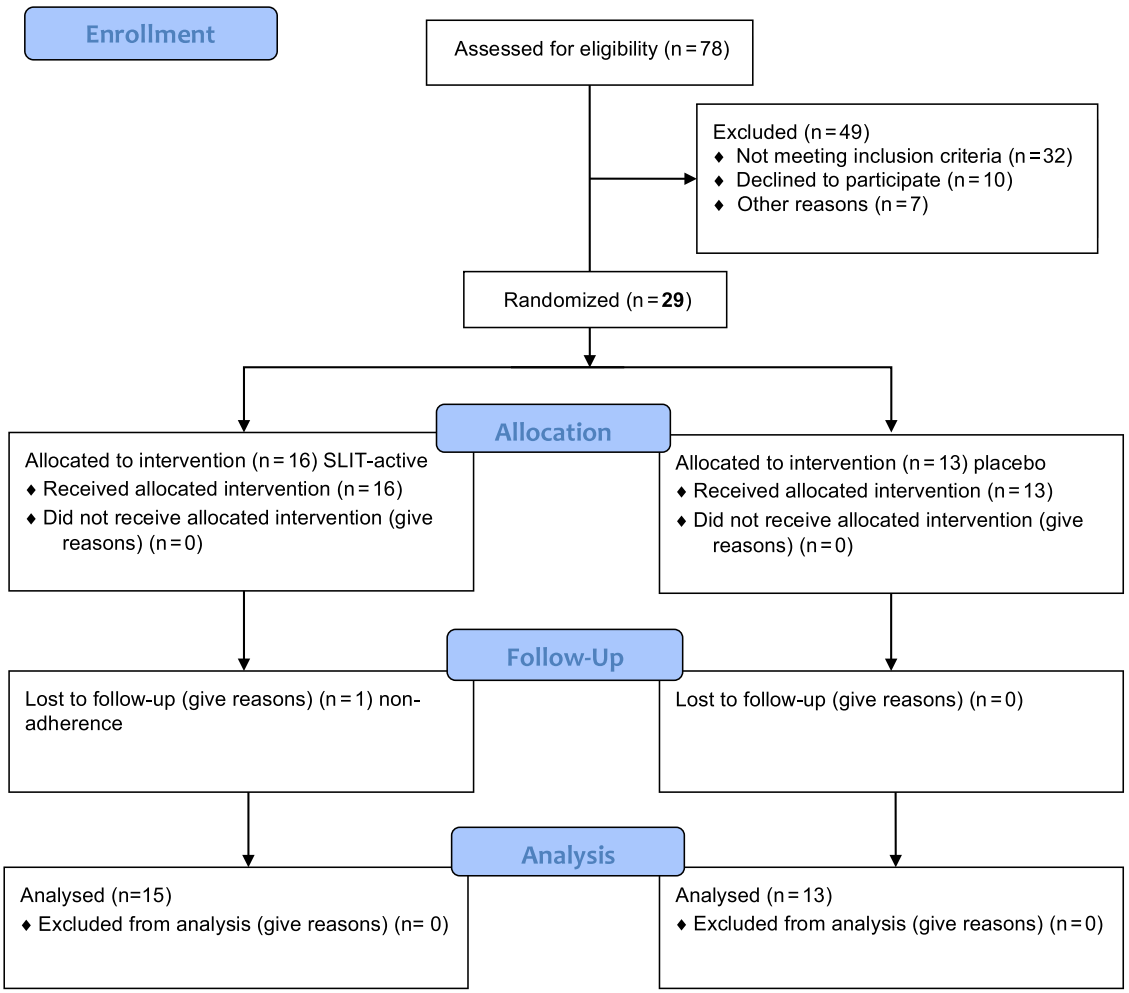

Figure 1. Number of participants assessed for eligibility who completed the study. SLIT, sublingual immunotherapy.

Download English Version:

https://daneshyari.com/en/article/8711909

Download Persian Version:

https://daneshyari.com/article/8711909

Daneshyari.com