Patient knowledge of immunotherapy before and after an educational intervention: a comparison of 2 methods

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Background: Immunotherapy is an invaluable therapy for allergic asthma, allergic rhinitis, and hymenoptera hypersensitivity. It is, however, not without risks.

Objectives: To examine patient knowledge regarding immunotherapy and to determine the most effective educational method to improve their knowledge by answering the following questions: Before educational intervention, what is the current knowledge level regarding allergy vaccinations of patients receiving immunotherapy? What effect does an educational encounter have on that level of knowledge? Which educational intervention—a one-on-one session vs a handout—if either, increases patient knowledge more?

Methods: An original, self-administered patient questionnaire was distributed to all patients receving immunotherapy. Patients were randomly assigned to a control group, an intervention group that received an educational handout monthly for 2 months, or an intervention group that had a one-on-one educational session with a physician or nurse practitioner. After 3 months, all patients completed an identical follow-up questionnaire. Pretest and posttest scores were compared for each group and among the different groups to determine which method was more effective. Repeated-measures analysis of variance was used to determine the effect of instruction type on differences in pretest and posttest scores.

Results: All 3 groups significantly improved their mean overall questionnaire scores ($P < .001$). The amount of change was greater in the intervention groups than in the control group, but it did not reach statistical significance ($P = .59$).

Conclusions: Baseline immunotherapy knowledge of allergy vaccination patients was better than expected, and further educational interventions did not significantly improve this knowledge.

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INTRODUCTION

Noon[1] and Freeman[2] introduced immunotherapy in 1911. The goal of immunotherapy is to decrease a patient's allergic response to allergens to which he or she is sensitive by subcutaneously injecting increasing amounts of the allergen(s) over time.[3,4] These allergens include not only aeroallergens, ie, pollens, but also potentially life-threatening allergens, as in the case of hymenoptera hypersensitivity. Immunotherapy is the only medical intervention that modifies the immune response. Immunotherapy is effective for treating allergic rhinitis, allergic asthma, and stinging insect hypersensitivity and, therefore, merits consideration in patients with these disorders.[5] Efficacy has been confirmed for the treatment of inhalant allergy attributable to pollen, fungi, animal allergens, arthropods such as dust mites, and insects such as cockroaches.[5] Allergen immunotherapy for allergic rhinitis has benefits even after immunotherapy is discontinued[6] and can reduce the development of asthma in children with seasonal rhinoconjunctivitis.[7] As allergic diseases increase in prevalence, the number of patients who seek medical care in the form of immunotherapy will also increase. However, despite these benefits, there are inherent risks associated with allergy vaccinations.[5]

The reported incidence of adverse reactions varies considerably and depends on the type of allergen vaccine, the patient population, and the treatment schedule used. The nonfatal adverse reaction rate ranges from less than 1% of patients receiving immunotherapy to 36.2% of patients receiving rush immunotherapy without pretreatment or monitoring.[8] The first death attributed to immunotherapy was reported in 1929 by Lamson.[9,10] Forty-seven fatalities were attributed to immunotherapy between 1959 and 1989.[8,11] A recent review of systemic reactions at the Allergy Clinic at Wilford Hall Medical Center, Lackland Air Force Base, TX, found 161 systemic reactions in 4 years, for a reaction rate of 0.8% per vaccination. No fatality has occurred at our clinic.

Risk factors for serious systemic reactions that have been identified include (1) a medical condition that reduces the ability to survive a systemic reaction, (2) compromised pulmonary function, (3) poorly controlled asthma, and (4) concurrent use of β-adrenergic blocking agents.[5] The Joint Task Force on Practice Parameters[5] has proposed guidelines to reduce the risk of anaphylaxis, including the following: patients should wait in the physician's office for 20 to 30 minutes after receiving an immunotherapy injection, an eval-

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uation of the patient's state of health before receiving an immunotherapy injection should be made, and dosage adjustments for reactions, new vials, etc, may be required. Finally, the guidelines recommend that patients who take β-blockers should not receive aeroallergen immunotherapy.

Patient education is an essential part of the treatment of chronic diseases.[12,13] Given the small but potentially fatal risks involved with immunotherapy, patients who undergo immunotherapy should have an understanding of the nature of immunotherapy and its risks and benefits. A prospective study[14] of 26 patients receiving immunotherapy addressed the role of patient education. Using a questionnaire, it was found that many patients did not understand important concepts related to safety and efficacy. After exposure to a patient education bulletin board, there was a significant increase in overall patient knowledge. A recent study by Sade et al,[15] published since our study was closed, examined the knowledge and expectations of patients receiving aeroallergen immunotherapy. Also a questionnaire-based study, it evaluated patient knowledge about the content, benefit, and risk related to the aeroallergen immunotherapy they were receiving. The authors concluded that there was a grave lack of knowledge and numerous misconceptions among many patients receiving aeroallergen immunotherapy and that more educational effort is needed to increase patient knowledge. Our purpose was to examine our patients' baseline knowledge regarding immunotherapy and, after randomization to 1 of 2 different educational interventions or a control group, to determine whether a specific educational intervention improved their knowledge. The following questions were addressed: Before educational intervention, what is the current knowledge level regarding allergy vaccinations of patients receiving immunotherapy? What effect does an educational encounter have on that level of knowledge? Which educational intervention—a one-on-one session vs a handout—if either, increases patient knowledge more?

METHODS

After obtaining patient consent in accordance with the local internal review board, an original, self-administered questionnaire was given to all patients 18 years and older actively receiving aeroallergen or venom immunotherapy at the Allergy Clinic at Wilford Hall Medical Center, a military-based tertiary care facility. The initial questionnaire consisted of 10 core multiple-choice questions (Fig 1) that were graded to evaluate baseline knowledge regarding allergy vaccinations and 12 additional questions regarding demographic and clinical information. Patients who completed the initial questionnaire were randomly assigned to 1 of 3 groups: a control group, a group that received a patient educational handout, and a group that received patient education from an educator (physician or adult nurse practitioner). Patients selected for the control group received only the immunotherapy education that is routinely given in the allergist's office. A follow-up questionnaire containing the 10 core questions was given to the control group 3 months later. The second group received an educational handout that addressed key information pertaining to immunotherapy. The educational handout was distributed initially and then again at months 1 and 2. These patients completed the follow-up questionnaire at the end of the third month. The third group met with an educator once during their wait time after receiving immunotherapy. This meeting was a one-on-one educational session for 10 to 15 minutes that covered the same material as the educational handout, with time allotted for questions. The third group completed the follow-up questionnaire 3 months later (Fig 2).

The 10 core questions were graded as correct or incorrect. The difference between the total number of correct responses to the preintervention and postintervention surveys was determined for each patient. To test whether the change in the number of correct responses differed among the 3 groups, a Kruskal-Wallis analysis of variance was performed. A Wilcoxon signed rank test was performed on each group, separately, to determine whether a significant change had occurred for that group. A change was considered statistically significant at $P < .05$.

RESULTS

Of approximately 350 active immunotherapy patients, 223 completed the initial questionnaire; 32 of these patients were withdrawn for being younger than 18 years and 32 were lost to follow-up. A total of 159 patients completed the follow-up questionnaire (Table 1). However, 1 of the 159 patients did not fully complete the 10 core questions; therefore, 158 patients were used in the pretest and posttest analysis.

Table 2 gives the demographic information for the 3 groups. There were no statistically significant differences among groups in sex, age, years receiving immunotherapy, number of patients receiving venom and aeroallergen immunotherapy, number of patients reporting a previous reaction to immunotherapy, or self-reported asthma. Patients younger than 18 years were excluded by study design, so the population age range was 20 to 73 years, with a mean age of 45.7 years. There were more women receiving immunotherapy than men (59% vs 40%), and this did not differ significantly among groups. The number of years receiving immunotherapy ranged from 0 (patients in the buildup phase) to 40 (mean, 4.4 years) and did not differ significantly among groups. Some patients were receiving lifelong venom immunotherapy for a history of life-threatening hymenoptera reactions. The number of patients receiving venom immunotherapy, aeroallergen immunotherapy, or both did not differ significantly among groups. Almost one third of the responding patients reported having had a systemic reaction to immunotherapy that required administration of injectable epinephrine, and one third claimed to have asthma.

Table 3 gives mean scores on the pretest and posttest questions for the total population and for each group. Repeated-measures analysis of variance was used to determine the differences in pretest and posttest scores. All 3 groups significantly improved their mean overall score ($P < .001$). The amount of change was greater in the intervention groups than

1. Please circle all of the true statements regarding allergy vaccinations.
   a. Allergy vaccinations are made from prepared solutions (extracts) of materials to which you are sensitive.
   b. The purpose of allergy vaccinations is to lessen your sensitivity.
   c. The purpose of allergy vaccinations is to decrease your allergy symptoms and/or need for allergy medications.
   d. There are no risks from receiving allergy vaccinations.

2. Please circle how long you should wait in the clinic after receiving your allergy vaccinations.
   a. Don't need to wait
   b. 15 minutes
   c. 30 – 60 minutes
   d. 2 – 4 hours

3. Please circle how often you should come in for your allergy vaccinations.
   a. Every 1 – 4 weeks
   b. Once every 2 – 3 months
   c. Once a year
   d. As often as needed

4. Please circle how long you should take allergy vaccinations for.
   a. One year
   b. 3 – 5 years
   c. Rest of your life
   d. As long as you want

5. Do you have asthma? Please circle: Yes No
If you have answered yes to question #5 regarding asthma:
   a. Should you tell the technician how your breathing is/how you are feeling before you get your vaccinations?
      Please circle: Yes No
   b. Should a breathing test be done before you get your vaccinations? Please circle: Yes No

6. Do you check that the vial being used is yours before the technician gives you your allergy vaccinations? Please circle: Yes No

7. When you come in for your allergy vaccinations do you verify the amount/dose that you are going to receive? Please circle: Yes No

8. Which of the following are signs or symptoms of a "reaction" to your allergy vaccinations? Circle all that are true.
   a. Runny nose or congestion or cough
   b. Wheezing or shortness of breath
   c. Lightheadedness
   d. Rash or welts or flushing
   e. Itchy skin or other part of the body
   f. Stomach cramping or diarrhea or vomiting
   g. Difficulty swallowing or lump in the throat
   h. Redness, warmth, or tenderness where the vaccination was given
   i. All of the above

9. What should you do if you think you are having a reaction?
Please circle all that are correct.
   a. Go home and don't worry about it
   b. Tell the technician
   c. Wait and see if it goes away
   d. Take my allergy medication
   e. Go to the emergency department if you are already home

10. Please circle which of the following medications you should not take if you are receiving allergy vaccinations.
   a. β = Blockers, such as Tenormin, Inderal, Lopressor
   b. Nasal steroids, such as Flonase, Nasacort, Nasonex
   c. Asthma medications, such as Proventil, Flovent, Azmacort
   d. None of the above

Figure 1. Core questions.

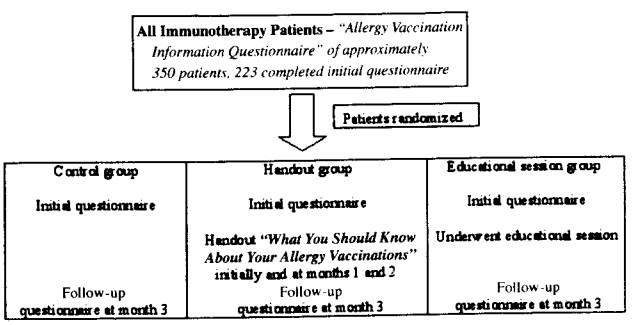

Figure 2. Study design.

Table 1. Distribution of Participants

	Control group	Handout group	Educational session group	Total
Initial questionnaire completed	89	72	62	**223**
Withdrawn for age	15	9	8	**32**
Lost to follow-up	17	12	3	**32**
Completed follow-up questionnaire	57	51	51	**159**

in the control group, but it did not reach statistical significance ($P = .59$). Figure 3 shows the improvement in questionnaire scores in each group over time. There was no difference when analyzed for patients receiving immunotherapy for less than 1 year vs longer than a year (data not shown).

Because most of our patients who have a systemic reaction that requires injectable epinephrine are then prescribed injectable epinephrine, patients were questioned about injectable epinephrine use. They were asked if they had been prescribed intramuscular epinephrine (Epi-Pen; Dey Laboratories, Napa, CA) or intramuscular epinephrine with chlorpheniramine (ANA-KIT; Hollister Stier, Spokane, WA) and, if so, whether they had been told how to use it, had been shown how to use it, and had used it (Table 4). Fifty-two percent of patients who answered the question had been prescribed an Epi-Pen. This was not statistically different

Table 2. Patient Demographics

Parameter	Control group	Handout group	Educational session group	Total (N = 159)*	P value between groups
Sex					
Male	23 (40)	18 (36)	23 (45)	64 (40)	.65
Female	34 (60)	32 (64)	28 (55)	94 (59)	
Age, mean (range), y	45.5 (20–73)	45.3 (20–70)	46.3 (25–72)	45.7 (20–73)	.92
Years receiving immunotherapy, mean (range), y	3.3 (0–29)	5.2 (0–23)	4.9 (0–40)	4.4 (0–40)	.11
Venom immunotherapy, No. (%)†	9 (16)	10 (20)	11 (22)	30 (19)	.74
Aeroallergen immunotherapy, No. (%)†	49 (86)	42 (84)	42 (82)	133 (84)	.84
Reports previous reaction to immunotherapy, No. (%)	13 (23)	16 (32)	16 (31)	45 (28)	.85
Patient-reported asthma, y	18 (32)	17 (34)	12 (24)	47 (30)	.56

* Some questionnaires were incomplete regarding demographic information.
† Some patients receive both pollen and venom immunotherapy.

Table 3. Study Results

	Control group	Handout group	Educational session group	Total
Pretest score, mean, %	76.5	77.5	77.2	77.0
Posttest score, mean, %	81.2	84.7	84.2	83.3
Improvement, %	4.7	7.2	7.0	6.3

among the groups. Of those prescribed an Epi-Pen, 95% reported that they were told how to use it, 83% indicated that they had been shown how to use it, and 11% claimed that they have used their Epi-Pen at some time. Only 4 patients (3%) had an ANA-KIT. All 4 recipients reported that they were told and shown how to use it, and 3 claimed that they have used it.

Patients were also queried regarding where they obtained information about their allergy vaccinations: written literature, other patients, the Internet, the prescribing physician, the allergy technician, or another source (Table 5). Forty-one percent of patients learned about immunotherapy from written literature, 14% from other patients, 7% from the Internet, 88% from their prescribing physician, 33% from an allergy technician, and 17% from other sources.

DISCUSSION

This randomized, prospective study showed statistically significant improvements in baseline immunotherapy knowledge in the 3 groups of patients studied. The improvement was not statistically significant in the 2 different educational intervention groups compared with the control group. At least 3 reasons could account for our findings. First, the baseline knowledge of our immunotherapy patients was higher than expected, and, therefore, we could not significantly improve on this. Our clinic has an extensive informed consent document for immunotherapy that incorporates most of the items covered by the questionnaire. All immunotherapy patients, regardless of their participation and randomization in this study, sign this document before starting immunotherapy and then annually. Second, all 3 groups improved their pretest to posttest scores. The mere act of completing the questionnaire could have educated the control group or sparked questions that led them to pursue self-education. The Hawthorne effect is a well-known phenomenon that states that merely by participating in a test, trial, or study the participants have a better experience, leading to a better result regardless of the treatment given. In addition, the control group continued to receive their immunotherapy in our clinic and were therefore exposed to other patients, technicians, and posted educational materials. In this regard, the control was not a true noninterventional control group but represented our baseline immunotherapy patients. This was believed to be more clinically applicable for determining whether we could improve on the baseline education already received. Third, it is possible that the forms of education we performed do not improve patient knowledge.

Multiple studies[16–20] have been published regarding the role of patient asthma education. Education of asthma patients usually leads to better control of the disease, fewer physician visits, less hospital and emergency department admissions, and fewer lost days from work. The authors concluded that an effective teaching and treatment program for asthmatic patients should include information about the disease, prevention and treatment of asthma attacks, and training in patient self-management of airflow limitation. In addition, patient education diminishes the frequency of asthma attacks and decreases the disability of the patients.[16] A 1999 review,[17] however, of 77 educational programs for adults with asthma that compared 94 educational interventions concluded that vital information about the content of the programs was lacking from published sources and that the interventions varied widely in both methods and content, making comparisons difficult. The findings suggested that a lack of consensus exists on effective patient education in asthma and that a meta-analysis was not feasible.[17]

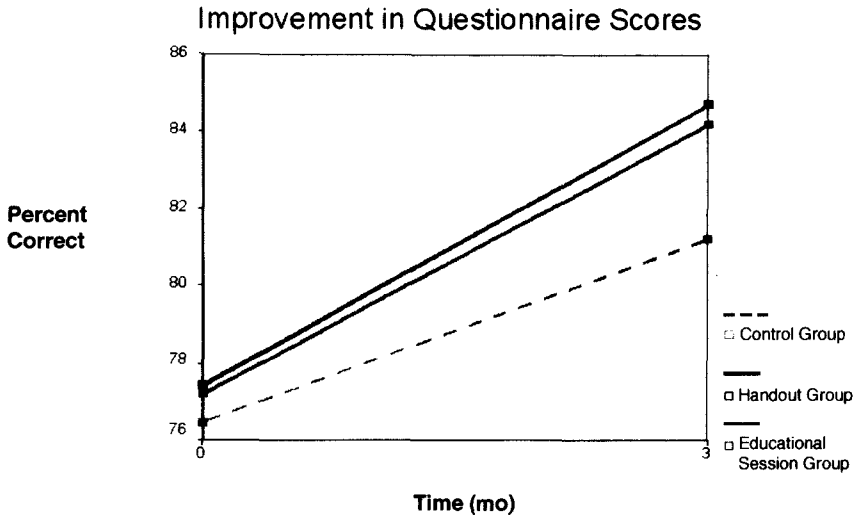

Figure 3. All 3 groups showed statistically significant improvement in pretest to posttest scores ($P < .001$); improvements in intervention groups were not significant compared with the control group ($P = .59$).

Table 4. Knowledge Regarding Injectable Epinephrine

Parameter	Control group	Handout group	Educational session group	Total (N = 159)	*P* value between groups
Have an Epi-Pen	24 (42)	32 (64)	26 (51)	82 (52)	.06
Were told how to use it	23 (96)	31 (97)	24 (92)	78 (95)	.98
Were shown how to use it	22 (92)	27 (84)	19 (73)	68 (83)	.25
Have used it	2 (8)	5 (16)	2 (8)	9 (11)	.60
Have an ANA-KIT	2 (3)	1 (2)	1 (2)	4 (3)	.87
Were told how to use it	2 (100)	1 (100)	1 (100)	4 (100)	NA
Were shown how to use it	2 (100)	1 (100)	1 (100)	4 (100)	NA
Have used it	1 (50)	1 (100)	1 (100)	3 (75)	.51

Abbreviation: NA, not applicable.

Table 5. Sources of Previous Immunotherapy Education*

Source	Control group	Handout group	Educational session group	Total (N = 159)	*P* value between groups
Written literature	21 (37)	21 (41)	23 (46)	**65** (41)	.67
Other patients	10 (18)	3 (6)	10 (20)	**23** (14)	.09
Internet	2 (4)	6 (12)	3 (6)	**11** (7)	.24
Prescribing physician	51 (89)	42 (82)	47 (94)	**140** (88)	.14
Allergy technician	16 (28)	19 (37)	18 (36)	**53** (33)	.59
Other	8 (14)	10 (20)	9 (18)	**27** (17)	.76

* Data are given as number (percentage) of patients.

Other studies have addressed the role of education in improving patient compliance. Compliance is essential to enable immunotherapy to be an effective mode of treatment for allergic rhinitis and allergic asthma. Previous investigations found that the allergist must be persuasive and convince the patient that immunotherapy will be helpful and that the better the educational approach, the more likely it is to succeed.[21] Factors associated with noncompliance relate to the illness, patient, physician, medication regimen, and treatment milieu. The physician's relation to the patient and the way he or she explains treatment can have powerful consequences on compliance. The most important contribution to compliance is the understanding a patient has of the illness, the need for treatment, and the likely consequences of both.[22] Excellent communication with the patient can improve compliance.[23]

Some recommendations have been made regarding the education of patients receiving immunotherapy.[24] It is essential for patients receiving allergen immunotherapy to understand the treatment principle, the frequency of injections, the duration of treatment, the risk and signs of adverse events, the magnitude of the efficacy, and the essential nature of patient compliance and to be fully involved in the decision-making process with respect to the administration of allergen immunotherapy.

A recent article[15] published since the close of our study used a questionnaire to evaluate knowledge and expectations of patients receiving aeroallergen immunotherapy. Patients were asked whether immunotherapy could be dangerous or have significant adverse effects: 33% replied that they did not know, 35% considered it to be entirely safe, 13% considered it to be sometimes associated with adverse reactions, and only 19% believed that it is rarely associated with significant risk or adverse effects. When the knowledge and expectation levels were compared with the duration of immunotherapy, patients in the first 6 months of immunotherapy had more knowledge of their conditions and the nature of treatment. Our study, however, found no difference between those in their first year of immunotherapy compared with those receiving immunotherapy for more than a year. Overall, Sade et al[15] concluded that there is "a grave lack of knowledge and numerous misconceptions among substantial numbers of patients receiving aeroallergen IT [immunotherapy]." The authors proposed that more educational effort is needed to increase patient knowledge before and during immunotherapy. An accompanying editorial,[25] noting the success of written action plans in asthma management, stated that the study strongly suggested that written information plans are required and that education on immunotherapy is needed at regular intervals.

Overall, our patients answered 77% of the questions correct on the pretest and 83% correct on the posttest. It is alarming, however, that when looking at the 2 topics we considered most important, only 33% initially identified all the possible signs and symptoms of a reaction listed and only 64% realized that β-blockers should not be taken while undergoing immunotherapy. Despite a better-than-expected outcome on the initial questionnaire, an uncomfortable proportion of patients lacked this crucial knowledge. Of all the symptoms listed, gastrointestinal symptoms (stomach cramping, diarrhea, and vomiting) were least recognized as possible symptoms during an allergic reaction. It is notable that the intervention groups significantly improved on this question compared with the control group ($P < .01$). The question regarding β-blocker use did not significantly improve in any group.

Education did make a difference in our study. The simple act of being reintroduced to information on a follow-up questionnaire, as in our control group, led to a significant improvement in knowledge. Patients in the handout and one-on-one educational session groups seemed to have greater improvement than the control group, but this was not statistically significant. With a larger study population it is possible that a statistically significant difference would be found. Likewise, had we conducted the posttest questionnaire at a later date, such as 6 months or 1 year, the improvement noted in the control group might not have achieved statistical significance. Additional studies will need to be conducted to answer these questions.

Allergen immunotherapy is the only treatment for allergic rhinitis and venom hypersensitivity known to alter the immune response. It plays a significant role in the treatment of allergic diseases. Owing to the inherent risks and long-term commitment required, a fully informed patient is desirable. Patient education is an essential part of disease management, and immunotherapy is no exception. Although our study did not show a statistical improvement, we will continue in our educational efforts.

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