



A Study on Compliance to Allergen Immunotherapy in Respiratory Allergy

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Financial Support: None declared
Conflict of Interest: None declared
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How to cite this article:

Gowda G, Pruthvi S, Upadhya KG, Nagaraj C, Parasuramalu BG. A Study on Compliance to Allergen Immunotherapy in Respiratory Allergy. Natl J Community Medicine 2018; 9(2):96-99

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Date of Submission: 19-06-17

Date of Acceptance: 12-02-18

Date of Publication: 28-02-18

ABSTRACT

Introduction: Respiratory allergic diseases requires administration of Allergen immunotherapy at frequent intervals for a period of time which is usually 3-5 years which makes compliance issues particularly relevant.

Objectives: To describe socio-demographic profile of study subjects and to assess various factors influencing compliance to allergen immunotherapy.

Methods: A prospective longitudinal study conducted at Allergy clinic, Department of Community Medicine, Kempegowda Institute of Medical Sciences, Bangalore. Data was collected by review of the individual records of all the patients who were started on allergen immunotherapy during January 2011 – December 2014 (3 years). Reason for discontinuation of treatment was collected through phone calls.

Results: There were 109 (53.96%) males and 93 (46.04%) females. Majority i.e. 146 (72.27%) were in the age group of 21- 40 years. There were 117 (57.92%) on allergen Immunotherapy for House dust mite only, 42 (20.79%) for pollen only and 43 (21.29%) for both house dust mite and pollen. 15 (7.43%) subjects have completed 3 years treatment, 125 (60.40%) are continuing treatment and 63 (30.69%) have discontinued treatment (Non-compliance). Commonest reasons for non-compliance were no improvement, afar hospital and adverse reactions.

Conclusion: Non-compliance to allergen immunotherapy was 30.69% and commonest reason for non-compliance was no improvement.

Key words: Respiratory allergy, compliance, allergen immunotherapy

INTRODUCTION

The management of respiratory allergies like allergic rhinitis and allergic asthma includes patient education, environmental control and allergen avoidance, pharmacotherapy, and allergen immunotherapy (AIT).^{1,2} Allergen-specific immunotherapy (AIT) is safe and effective for the treatment of allergic rhinitis and allergic asthma. Its safety and efficacy has been evaluated by various randomized controlled trials.³ Compared with pharmacologic therapies, which provide temporary relief of aller-

gy symptoms, allergen specific immunotherapy is the only treatment which alters natural history of the disease and gives delayed long term benefits. AIT is cost effective compared to pharmacotherapy, decreases the risk of developing asthma and new allergies and produces sustained clinical benefits after completion of a treatment course of 3 to 5 years.^{4,5}

Allergen specific immunotherapy is recognized as effective treatment for respiratory allergy.¹ It requires administration of gradually increasing dos-

es of the specific allergen at frequent intervals for a period of time which is usually 3-5 years.^{2,5} It requires frequent visits to hospital for administration of allergen shots. It does not give immediate symptom relief. Hence it requires a substantial commitment from the patient for the success of the treatment. These make compliance issues particularly relevant. Poor compliance leads to poor therapeutic outcome of the therapy. There are only few studies available on patient's compliance to allergen immunotherapy in India. Hence this study was undertaken with the objective of to identify the compliance to allergen immunotherapy and factors affecting compliance.

METHODOLOGY

A prospective longitudinal study was conducted in an Allergy clinic of a medical college hospital in southern India. A total of 203 study subjects diagnosed as Allergic Rhinitis (based on ARIA guidelines)⁶ and/or bronchial Asthma (based on GINA guidelines)⁷ recruited between January 2011-December 2014 (4yrs). Those who completed at least six months of treatment at the time of analysis were included as study subjects. Institutional ethical clearance was taken before the start of the study. All the patients signed informed consent before the start of treatment.

Separate/individual case record diary was maintained for each patient who started on immunotherapy. The details regarding socio-demographic characteristics, duration of symptoms related to allergy, diagnosis, comorbid illnesses, type of allergen sensitivity, regimen of immunotherapy and date of initiation of immunotherapy were noted.

Study subjects who have been advised to stop immunotherapy by allergist after 3 years of treatment or continuing treatment after six months of starting of the treatment were considered as compliant. Those subjects who discontinued treatment during the course for more than 2 months were labeled Non-compliant. Those subjects who discontinued treatment in between were contacted through telephonic interviews to find out the possible reasons for discontinuing the treatment. All the subjects were asked for self-perception of improvement of symptoms following immunotherapy.

Data was entered in Microsoft excel and was analyzed in SPSS 16.0 version. Descriptive statistics like mean, percentage and standard deviation were calculated. Chi-square test, Odds ratio were computed for compliance to allergen immunotherapy in association with variables: sex, age, type of disease, regimen, type of allergen sensitivity.

RESULTS

A total of 203 subjects were recruited during the follow up period of four years. 108 (53.20%) were males and 95(46.80%) were females. Most, 75 (36.95%) of the study subjects were in the age group of 31 to 40 years with mean age \pm SD of the subjects was 32.50 ± 10.03 . Out of 203 subjects, majority 103 (50.74%) were graduates and 71(35.03%) of the study subjects were professionals (**Table -1**).

There were 113(55.66%) of the subjects diagnosed with allergic Rhinitis only, 65(32.02%) with allergic Rhinitis and allergic bronchial asthma and 25(12.31%) with Allergic Rhinitis and other allergic disorders (Allergic conjunctivitis, chronic urticaria and atopic dermatitis). There were 124(85.19%) subjects sensitive to dust mites only, 44(21.67%) to pollens only and 35(17.24%) to both dust mites and pollens. Out of 203 subjects who started on immunotherapy, 34(16.74%) were on conventional regimen, 99(48.76%) on cluster regimen and 70(34.48%) on rush regimen as per patient convenience. Chi-square test was applied to see the association between compliance and various clinico-demographic factors. It was found that subjects on conventional immunotherapy regimen were more compliant compared to rush immunotherapy regimen and it was statistically significant ($p < 0.05$) (**Table 2**).

Table 1: Baseline Characteristics of study subjects

Parameters	Number (%)
Age (Yrs)	
21-30	71 (34.98)
31-40	75 (36.95)
Mean \pm SD	32.50 \pm 10.03
Sex	
Male	108 (53.20)
Female	95 (46.80)
Education -Graduate	103 (50.74)
Occupation -Professional	71 (35.03)

Out of 203 study subjects who started on Immunotherapy 15(7.39%) of the study subjects completed 3 years of treatment and had stopped treatment as per advice by the allergist. There were 125(61.58%) of study subjects still continuing the treatment. Those who completed treatment and continuing treatment after six months of starting of treatment were considered as compliant and it was 68.97%. There were 63(31.03%) of the study subjects who discontinued treatment were considered as non-compliant.

Among 63 non-compliant subjects, 8 could not be contacted through phone call. Remaining 55 were contacted through telephone call to find out the reason for non-compliance.

Table 2 - Univariate analysis of factors related to compliance

Factors related to compliance	Total (n= 203)	Compliant (n= 140, 68.97%)	Non- Compliant (n = 63, 31.03%)	p value**
Sex				
Male	108 (53.20)	77(71.2)	31(28.8)	0.53
Female	95 (46.80)	63(66.31)	32(33.69)	
Age				
<20 yrs	22 (10.84)	15(68.18)	7(31.82)	0.92
20-40 yrs	146 (71.92)	101(69.17)	45(30.83)	
>40 yrs	35 (17.24)	24(68.57)	11(31.43)	
Type of disease				
Allergic Rhinitis only	113 (55.67)	76(67.25)	37(32.75)	0.55
Allergic Rhinitis with Others	90 (44.33)	64(71.11)	26(28.89)	
Type of Allergen sensitivity				
Pollens	44 (21.68)	29(65.90)	15(34.10)	0.74
Dust mites	124 (61.08)	85(68.54)	39(31.46)	
Pollens and Dust mites	35 (17.24)	26(74.28)	9(25.72)	
Regimen				
Conventional	34 (16.75)	28(82.35)	6(17.65)	0.1
Cluster	99 (48.77)	67(67.67)	32(32.33)	
Rush	70 (34.48)	45(64.28)	25(35.72)	

*figures in parenthesis indicate percentage ** chisquare test

The most common reason for non-compliance was inconvenience by distance (23, 41.82%), followed by no improvement (21, 38.18%), adverse reactions (7, 12.73%), improvement of symptoms (7, 12.73%), inconvenience by time (7, 12.73%), and pregnancy (3, 5.45%).

Table 3 - Reason for non-compliance to treatment (n = 63)

Reasons for non-compliance*	Number (%)
Inconvenience by distance	23 (41.82)
No Improvement	21 (38.18)
Adverse reactions	7 (12.73)
Time inconvenience	7 (12.73)
Improvement	7 (12.73)
Pregnancy	3 (5.45)

* Multiple responses; 8 patients were not able to contact

DISCUSSION

Compliance is the degree of constancy and accuracy with which a patient follows a prescribed regimen. Compliance is the important issue in achieving the full benefit of immunotherapy. Lack of compliance is the one of the reason for poor clinical outcome.

The overall compliance rate in this study is 68.97%. A recent study by Musa et al found 58.7% compliance rate in patients receiving subcutaneous immunotherapy.⁸ A study conducted by More DR et al at Military medical center in America found compliance of 77.4% to allergen immunotherapy.⁹ The first studies published in the 1990s reported rates of lack of compliance surprisingly high, corresponding to about 50%, in both adults (Cohn and Pizzi 1993) and children (Lower et al 1993).¹⁰

Compliance was evaluated for various demographic factors. In this study compliance was more in males when compared to females but that was not significantly associated. In a study by Mahesh PA et al in India also observed compliance was more in males compared to females but it was statistically significant.¹¹ In this study, there was no difference in compliance rate with respect to age groups, type of allergic diseases, and type of Allergen sensitivity. A study by More DR et al observed younger and older age groups (<18 and >45 yrs) were more compliant(p<0.001).⁹ This study also did not find difference in compliance rate with respect to type of allergic diseases. There was no difference in adherence rate by diagnosis by Mahesh PA et al in India.¹¹ Compliance rate was compared regarding different regimens of subcutaneous immunotherapy and it was found patients receiving conventional regimen (82.35%) were more compliant than rush regimen (64.28%) (p<0.05). A similar finding was observed in study by More DR et al.⁹

In this study the most reason for non-compliance was inconvenience by distance (41.82%) followed by no improvement (38.18%). More DR et al found the most common reason for non-compliance were inconvenience (34.5%), precluding medical condition (18.2%), and adverse systemic reaction (16.4%). A study by Incorvaia C et al found inconvenience to treatment, followed by adverse drug reactions, cost and feeling of improvement.¹² In a study by Sánchez J found difficulty in complying with treatment, lack of opinion of efficacy, adverse reactions were reasons for drop out from treatment.¹³

CONCLUSION

Compliance to Allergen immunotherapy is substantially determined by various factors like demographic, type of disease, regimen used which will determine the outcome of treatment. Addressing the factors associated with poor compliance will increase clinical outcome.

Acknowledgements

We thank all staff of allergy clinic, Department of Community medicine, Pulmonary medicine and Otorhinolaryngology, Kempegowda Institute of Medical Sciences and hospital, Bangalore. We are also thankful to study subjects.

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