

A Study of Effect of Subcutaneous Immunotherapy in Treatment of Allergic Rhinitis and Allergic Asthma in Udaipur, India

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ABSTRACT

Background: Aeroallergens are responsible for the development of allergic respiratory diseases like allergic rhinitis and allergic asthma. These aeroallergens are pollen; spores, grass weeds, house dust mite, dust, fungus and insects. In India, there is a pollen calendar according to different areas and season. Allergic immunotherapy plays a major role in treatment of allergic diseases like, allergic rhinitis, and allergic asthma, urticaria and allergic conjunctivitis. Allergic immunotherapy involves administration of allergen to which patient is sensitive, for the purpose of modulating the untoward immune response to that allergen and alleviating allergic system. Subcutaneous immunotherapy is a type of allergic immunotherapy. In Udaipur, one observational study was done to study the effect of subcutaneous immunotherapy in treatment of allergic respiratory diseases like allergic rhinitis and allergic asthma etc.

Materials and Methods: Subcutaneous immunotherapy was given to 850 respiratory allergic patients who were found positive by intradermal allergic testing kit contain five allergen extract depend on history of patients with marked positive skin reaction (3+/4+) and ready for subcutaneous immunotherapy in last 15 years from 2001 to 2015.

Results: Among 850 patients (357 male, 493 female), 617 followed complete immunization schedule. From 617, 207 male

and 227 female having complete relief from symptoms and medication (P value < 0.0001) for allergic rhinitis and allergic asthma.

Conclusion: Subcutaneous immunotherapy plays an important role in treatment of allergic respiratory diseases. Effect of subcutaneous immunotherapy depends on proper selection of allergens and its scheduled desensitization. one should go for immunotherapy if not improved by medication.

Key Words: Intradermal Allergic Testing, Respiratory Allergic Diseases, Subcutaneous Immunotherapy.

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INTRODUCTION

Aeroallergens are responsible for the development of allergic respiratory diseases like allergic Rhinitis and allergic asthma. These aeroallergens are pollen, spores grass weeds, house dust mite, dust, fungus and insects. In India, there is a pollen calendar according to different areas and season. Allergic immunotherapy plays a major role in treatment of allergic diseases like, allergic rhinitis, allergic asthma, urticaria and allergic conjunctivitis. Approximately 20% to 30 % of total population suffers from at least one of these allergic diseases in India.¹ Initially described by Noon² and Freeman³ a century ago, allergen-specific immunotherapy (SIT) involves the repeated administration of allergen extracts to atopic individuals with the goal of inducing

clinical and immunologic tolerance. Allergic immunotherapy involves administration of allergen to which patient is sensitive, for the purpose of modulating the untoward immune response to that allergen and alleviating allergic system. Subcutaneous immunotherapy is a type of allergic immunotherapy. Subcutaneous immunotherapy (SCIT) is a unique therapy for allergic disease because it provides symptomatic relief while modifying the allergic disease by targeting the underlying immunological mechanism. SCIT is a safe therapeutic intervention when it is prescribed to well-selected patients, and given in a specialist clinic with adequate facilities and by trained medical personnel. SCIT is associated with a risk of systemic side effects

and anaphylaxis. SCIT can produce both local and systemic adverse reactions; however, in the majority of cases these symptoms are readily reversible if recognized early and with prompt treatment. In Udaipur, one observational study was done to study the effect of subcutaneous immunotherapy in treatment of allergic respiratory diseases like allergic rhinitis and allergic asthma confirmed with allergic skin testing for different allergens.

MATERIALS AND METHODS

Study was carried out in 1050 patients of respiratory allergic disease (allergic rhinitis and allergic asthma) aged between 15 to 55 years at RNT medical college, Udaipur Rajasthan India in last 15 years. These patients were not well controlled with conventional treatment, undergo for allergy test and later on immunotherapy.

Skin Sensitivity Test: All the patients underwent intradermal allergy test for aero-allergen. Extract includes 51 pollens, 20 fungi, 20 insects, 12 dusts, 6 dander's, 7 fabrics and feathers, 9 woods

and house dust mite. The skin reaction was graded after 20 min according to criteria propose by V P chest institute, Delhi.¹ 30 patients excluded out of 1050 patients due to severe adverse reactions.

IMMUNOTHERAPY ADMINISTRATION AND ITS SCHEDULE

Each patient was given their immunization schedule containing desensitization of mixture that is not more than 5 allergens at a time subcutaneously in their increasing dose weekly according to, Delhi CSIR. Every patient were explained about benefits risk and cost also about its efficacy and its duration of treatment, risk of anaphylaxis and importance of adhering of immunotherapy schedule. Among 1020 patients, 850 patients were ready for subcutaneous immunotherapy for allergic rhinitis and allergic asthma. Every patient was given their immunotherapy chart/ Hypo sensitization chart attached with. Concentration of antigen was given subcutaneously according to Indian college of allergy asthma and applied immunology, V P Chest institute, Delhi.¹

**IMMUNOTHERAPY/HYPOSENSITIZATION CHART
DOSAGE CHART**

Date Month Year	Dose and concentration of Antigen	One line progress not regarding severity and frequency of Asthma or Rhinitis	Medication and symptoms score increased, same or decreased
1	1:5000 0.1 ml to 0.9 ml	Two injections a week 4.5 weeks	
2	1:500 0.1 ml to 0.9 ml	Two injections a week (After 1) 4.5 weeks	
3	1:50 0.1 ml to 0.5 ml	Once in a week (After 2) 9 weeks	
4	1:50 0.6ml Each	Once in two weeks (After 3) 18 weeks	
5	1:50 0.7ml Each	Once in three weeks (After 4) 18 weeks	
6	1:50 0.8 ml Each	Once in 4 weeks (After 5) 28 weeks	

After giving subcutaneous injection patients were asked to set for 30 minutes to watch for any reaction like induration, erythema, edema, itching, Bronchospasm etc. Patients were asked about their in decrease in symptoms and medication score or not. At the end of the study they were evaluated as cured, No improvement and mild or moderate improvement with respect to their symptoms and medication score.

Data collected in the case record form transferred to EXCEL format and analyzed statistically. Statistical analysis was done with ANOVAs one way variance and chi square in SPSS 22 version. Data analyzed were considered to be significant if p value is <0.001.

Exclusion Criteria

Pregnant females, children, persons with their co morbidities, patients with immunological diseases & coexisting uncontrolled severe asthma.

RESULTS

Total 850 patients were ready for subcutaneous immunotherapy. From 850, total no of male patients were 357 and female patients were 493. Total six sitting were planned in immunization schedule. From first sitting(1: 5000) to end of third sitting (1:50)160 patients were lost on follow up and remaining continued, among them 20 male patients and 31 female patients having mild improvement in medication and symptom score and 26 male patients and 33 female patients having moderate improvement in medication and symptoms score. (Table 1) Likewise at the end of six and the last dosing schedule total no patients remained were 617 (male 233, female 384), total 70% patients were being symptoms and medication free. p value <0.0001 (Table 2) with odd ratio 5.626 with 95% CI 3.567-8.873 indicates that subcutaneous immunotherapy is 5 times more effective in cured patients with respect to patients having no improvement.

Table 1: Number of patients adhering to treatment protocol along with improvement perceived sitting wise.

Category	1 st to 3 rd SITTING		4 th SITTING		5 th SITTING		6 th & Final SITTING	
	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE
MILD*	5.6%(20)	6.28%(31)	21.07%(59)	15.85%(65)	21.8%(56)	18.7(72)	33%(77)	29.1%(112)
MOD*	7.28%(26)	6.69%(33)	24.6%(69)	20%(82)	28.5%(73)	22.6%(87)	34.7%(81)	27.3%(105)
LFU	21.56%(77)	16.83%(83)	8.57%(24)	6.34%(26)	8.9%(23)	6.5%(25)	0	0
CONTI	65.54%(234)	70.18%(346)	45.7%(128)	57.8%(237)	40.6%(104)	52%(200)	32.1%(75)	43.8%(167)
Total	357	493	280	410	256	384	233	384
χ²value, DF	3.382, 3		9.899, 3		8.358, 3		8.083, 3	
P value	0.336		0.019		0.039		0.018	

* = mild improvement and Moderate improvement respectively with respect to their medication and symptom score, LFU=lost on follow up, CONTI=Continued

Table 2: Final outcome of treatment (6th sitting)

Outcome	Male	Female	χ ² value, DF	P Value
Cured	207	225		
No Improvement	26	159	63.197, 1	<0.001
Total	233	384		

DISCUSSION

In this study we evaluated decreased in medication score and symptoms score for monitoring of subcutaneous immunotherapy .An important consideration in assessing outcomes is that there is interdependence between allergic symptoms and the use of antiallergic medication.

The WAO Taskforce recommendation clearly states that both scores should not be evaluated separately but be calculated in a combined score.⁴ The use of a combined score was endorsed by the EMA guidance, which stated that "a weighted sum of the symptom and medication score" shall be used.⁵ Again, currently there is no standardized and widely accepted method for the reporting of combined symptom and medication scores.⁶

In this study, maximum duration of subcutaneous immunotherapy was two years according to Indian college of Allergy, Asthma and Applied immunology, V P Chest institute, Delhi.

One prospective, randomized, controlled, open-label study of 147 children, aged 16–25 years, evaluated the effect of a 3 year course of grass and/or birch pollen SCIT on the development of asthma compared with pharmacotherapy alone (referred to as the Preventive Allergy Treatment or PAT study).⁷⁻⁹ SCIT was associated with a significantly lower incidence of asthma compared with pharmacotherapy alone at the end of treatment and at 5 and 7 years after discontinuation (OR: 2.5; 95% CI: 1.1–5.9 at 7 years).⁷ The authors concluded that SCIT administered for 3 years results in a long-term preventive effect on the development of asthma.

In this study a mixture of not more than five allergens were given subcutaneously at a time, One important variable in the administration of SCIT is the use of a single or multiple allergens. For example, allergy/immunology specialists in the United States generally administer mixtures of all of the major allergens (or a representative of each group of allergens) to which the patient has been shown to be sensitive.

In contrast, it is common in Europe is to administer only the one or two allergens that appear to cause the most symptoms for

that individual patient. Most of the studies of SCIT efficacy used a single allergen, and thus the efficacy of multiple-allergen SCIT has not been extensively studied. One literature review of 11 trials of SCIT found that the use of either one or two allergens was effective, but controlled trials involving higher numbers of allergens are lacking.¹⁰

CONCLUSION

Subcutaneous immunotherapy plays an important role in treatment of allergic respiratory diseases like allergic rhinitis and allergic asthma. Effect of subcutaneous immunotherapy depends on proper selection of allergens and its scheduled desensitization. Over all, if administered in appropriate settings, subcutaneous immunotherapy is safe and well tolerated. It also depends on trained physician who handle all the adverse effect associated with subcutaneous injection .one should go for subcutaneous immunotherapy for allergic respiratory diseases like allergic rhinitis and allergic asthma, if not improved by medication.

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