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Impact of patient counselling on quality of life in patients under treatment with sublingual immunotherapy with house dust mite allergen

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Abstract

An allergy is an exaggerated immune response by human immune system on exposure to certain foreign harmless substance. Sublingual Immunotherapy (SLIT) is a newer form of treating house dust mite allergy that is promising for a permanent cure. The Quality of Life (QoL) in patients on SLIT is a highly significant consideration for therapy continuity & ultimately the cure from allergy. Patient counselling plays a major role in patients on SLIT as it improves the patient's medication-taking behavior and thereby significantly enhance the QoL in patients with allergies. With respect to the above mentioned points, a prospective interventional study on "Impact of patient counselling on Quality of Life in patients under treatment with sublingual immunotherapy with house dust mite allergen" was carried out at Bangalore allergy centr for a period of 6 months. A total of 70 patients were recruited in the study according to the inclusion criteria. Patient education and counselling was provided using patient information leaflets available in the hospital regarding their medication usage. Rhinoconjuntivitis Quality of Life questionnaire and Dermatology Quality of Life index were used to assess the Quality of Life. Overall Quality of Life in adults ($p<0.001$), adolescents ($p<0.001$) and pediatrics ($p=0.003$) improved significantly during follow-up compared to baseline. In the adolescent age group, eye symptoms ($p=0.115$) and emotional stability ($p=0.628$) did not show statistically significant improvement following intervention. In the pediatric age group, the practical problems ($p=0.260$), nose symptoms ($p=0.243$) and other problems ($p=0.438$) (irritability, tiredness, headache, thirst) did not show a statistically significant improvement following intervention. Overall, 16 patients who had skin complications showed a statistically significant improvement in DQLI scores ($p=0.018$) following intervention. At the end of the study, no adverse reactions following SLIT therapy were observed. Therefore, there was a positive impact of patient counselling by Pharma-D research students on Quality of Life in patients under sublingual immunotherapy with house dust mite allergen.

Keywords: Sublingual Immunotherapy; Quality of life; House dust mite; Patient counselling.

Introduction

An allergy is an exaggerated immune response produced by the body to a foreign substance that is normally harmless. These foreign substances are usually termed as "allergens". In normal individuals, on exposure to these allergens no immune response is produced.

Immunity is the capability of multicellular organisms to resist harmful microorganisms. Immunity can be adaptive or innate [1].

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One of the most common type of allergy is House Dust Mite allergy. House Dust Mites are microscopic insect like pests that generate some of the most common indoor allergens that can cause asthma or allergic reactions in people. The most common type of House Dust Mites are *Dermatophagoides pteronyssinus*, *Dermatophagoides farinae* and *Blomia tropicalis* [2].

The complications that arise from house dust mites are allergic rhinitis, acute nasal bronchitis, allergic conjunctivitis, atopic dermatitis and chronic urticaria.

Most types of allergies are usually diagnosed using diagnostic tests such as complete blood count, enzyme linked immune sorbent assay, radio allegro sorbent test and skin prick test. Amongst these tests, the skin prick test is the most commonly used diagnostic tool. Form this test, the type of allergen that a patient is allergic can be determined. The test involves application of a drop of allergen on the forearm after which the surrounding area is pricked using a lancet and the patient is observed for any erythema or itching around the area of application. Any presence of redness or itching surrounding the area of the application suggest that the patient is sensitive to the specific allergen [3].

Allergies can be treated using antihistamines, corticosteroids, intranasal anticholinergics, oral decongestants, intranasal cromolyn and leukotriene receptor agonists which gives a short time relief [4].

Immunotherapy in the form of subcutaneous immunotherapy and sublingual immunotherapy that is to be taken for a period of three to five years is said to produce a permanent cure for the allergy. Sublingual immunotherapy involves introduction of a known allergen into the mucosal layer of the buccal cavity in order to induce tolerance to the allergen [5].

Sublingual immunotherapy is patient-specific, it is based on the percentage of how much the patient is allergic towards the specific allergen. The SLIT is made according to the patient's allergen percentage that is shown through skin prick test [6].

WHO defines Quality of Life as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" [7].

Quality of life in patients are measured using HRQoL scales in which various domains (aspects) of life will be assessed to evaluate the overall quality of life. A successful treatment option will improve the HRQoL of the patients.

The Rhinoconjuntivitis Quality of Life Questionnaire (RQLQ) is used to measure the functional problems (physical, emotional, social and occupational) with either seasonal or perennial rhinoconjuntivitis of either allergic or non-allergic origin [8].

The Dermatology Life Quality Index (DLQI) is designed to measure the health-related quality of life of adult patients suffering from a skin disease. The DLQI consists of 10 questions concerning patients' perception of the impact of skin diseases on different aspects of their health-related quality of life over the last week [9].

QoL is a matter of concern in case of chronic conditions such as house dust mite allergy. QoL in case of patients suffering from allergic conditions is usually reduced due to the long-term disturbances in the daily activities and social life, the need for additional precautions causes irritability and discomfort. Allergic conjunctivitis causes irritation in the eyes which might lead to use of OTC medications like artificial tears, antihistamine eye drops etc.

Patient counselling can be a very useful tool in improving the adherence to SLIT, and in turn improve QoL in patients suffering from house dust mite allergies. Counselling and educating the patients about proper technique of administration of the SLIT, precautionary measures to be taken during an acute allergic reactions and explaining the benefits of good adherence to SLIT will help improve the patients QoL in a significant way.

Aim and Objectives

Aim

To study the impact of patient counselling on Quality of Life in patients under treatment with sublingual immunotherapy containing house dust mite allergen.

Objectives

1. Primary objectives

- To assess the quality of life in patients.
- To evaluate whether intervention in the form of patient counselling improves the Quality of Life.

2. Secondary objectives

- To report any adverse reactions following sublingual immunotherapy.
- To understand clinical presentation of various allergic conditions.

Methodology

The study was carried out at Bengaluru Allergy Centr, Bangalore after obtaining the ethical clearance from Institutional Ethical Review Board of the hospital and using the Standard Informed Consent form available in the hospital.

Study design

Hospital based prospective interventional study.

Source of data

Data was collected from patient's case sheet and lab reports of the patient (skin prick test).

Inclusion criteria

Both genders of all age groups who were allergic to house dust mite and who were on SLIT therapy for 3 months.

Exclusion criteria

Patients who were not willing to give the details and patients who had withdrawn from sublingual immunotherapy.

Method of collection of data

According to inclusion criteria, patients were enrolled, past medical history was obtained and the diagnosis of each patient was noted. 70 patients who were included in the study were divided into 3 age groups namely pediatric (6-12 years), adolescent (12-17 years) and adults (17-70 years).

The clinical presentation of the patient's condition was carefully observed and baseline counselling was done on the condi-

tion of the allergy, duration, frequency, route of administration and continuity of the therapy for patients who have taken the treatment for a period of 3 months and Quality of life of the patient was assessed using Rhinoconjuntivitis Quality of Life Questionnaire (RQLQ) and the response was documented.

One-to-one counselling was done based on standard brochure which was available in the hospital and based on physician instructions.

Follow-up was done after 2 months from the baseline counselling by re-administering RQLQ scale for Quality of Life assessment and responses were documented.

Patients were enquired for any adverse drug reactions following treatment with SLIT.

Results

In our study, male patients were predominant compared to female patients (Figure 1). Adult patients were maximum followed by adolescents and pediatrics (Figure 2). Out of 70 patients, 5 (7.14%) patients were smokers and remaining 65 (92.8%) were non smokers (Figure 3), 6 (8.5%) patients had a history of alcohol use (Figure 4). In a total of 70 patients, 4(5.7%) patients had a family history of allergies in 1st degree relative, 15 (21.4%) in 2nd degree relative, 4 (5.7%) in both 1st and 2nd degree relative and 47 (67.1%) did not have any family history of allergies (Figure 5).

Out of 70 patients, 40 (57.14%) patients were sensitive to both *Dermatophagoids farinae* and *Dermatophagoides pteronyssinus* followed by 14 (20%) patients who were sensitive to both *Dermatophagoides pteronyssinus* and *Blomia tropicallis*. 12 (17.14%) patients were sensitive to *Dermatophagoides pteronyssinus* and 4 (5.71%) patients were sensitive to *Dermatophagoides farinae* alone (Figure 6).

Out of all the patients, 70% of the patients had nasal symptoms (runny nose, sneezing, cold, cough and wheezing) , 22% of the patients had skin symptoms and 8% of the patients had eye symptoms (Figure 7).

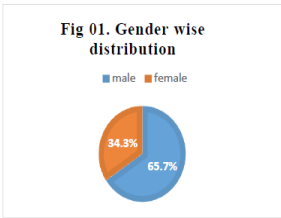

Fig 01. Gender wise distribution

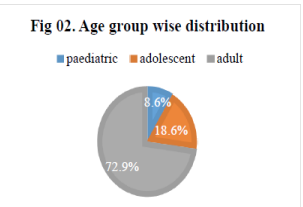

Fig 02. Age group wise distribution

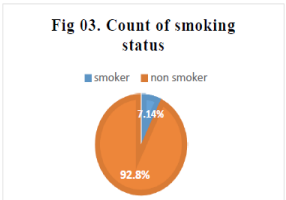

Fig 03. Count of smoking status

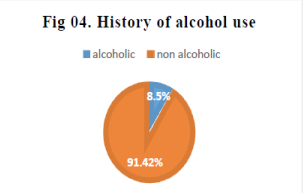

Fig 04. History of alcohol use

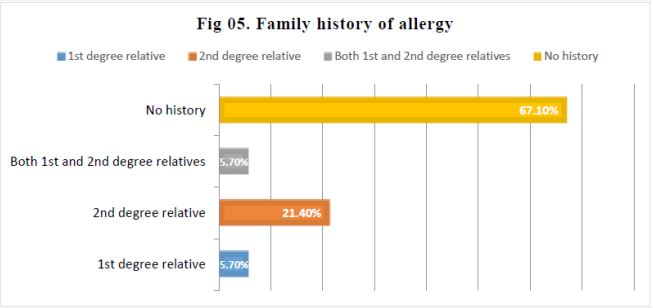

Fig 05. Family history of allergy

Fig 06. Distribution based on Skin prick test results.

Out of 70 patients, 40 (57.14%) patients were sensitive to both *Dermatophagoids farinae* and *Dermatophagoides pteronyssinus* followed by 14 (20%) patients who were sensitive to both *Dermatophagoides pteronyssinus* and *Blomia tropicallis*. 12 (17.14%) patients were sensitive to *Dermatophagoides pteronyssinus* and 4 (5.71%) patients were sensitive to *Dermatophagoides farinae* alone (Figure 6).

Fig 06. Distribution based on Skin prick test results.

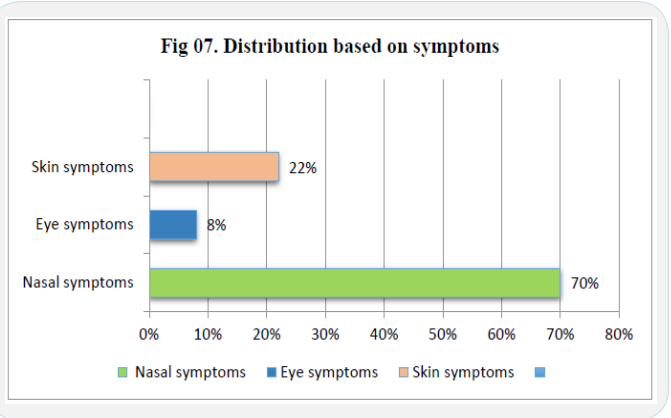

Fig 07. Distribution based on symptoms

Out of all the patients, 70% of the patients had nasal symptoms (runny nose, sneezing, cold, cough and wheezing), 22% of the patients had skin symptoms and 8% of the patients had eye symptoms (Figure 7).

Table 1: Number of patients with skin complications.

Skin complications	No of patients	Percentage
Chronic urticaria	7	43.75%
Dermatitis	9	56.25%
Total	16	100%

Out of all the patients who had skin complications, 9 (56.25%) patients suffered from dermatitis and 7 (43.75%) of patients suffered from chronic urticaria.

Table 2: Comparison of Rhinoconjuntivitis Quality of life Questionnaire (RQLQ) scores at baseline and follow up in pediatric patients.

RQLQ in Pediatrics Domains	Intervention	N	Mean	SD	T	*P*
Nose Symptoms	Baseline	6	3.3333	3.93277	1.323	0.243
	Follow up	6	1.0000	1.26491		
Eye Symptoms	Baseline	6	8.0000	7.58947	2.618	0.047
	Follow up	6	0.83333	1.32916		
Practical Problems	Baseline	6	4.1667	3.37145	1.270	0.260
	Follow up	6	1.83333	2.22860		
Other Symptoms	Baseline	6	3.0000	3.34664	0.843	0.438
	Follow up	6	1.3333	2.22860		
Activity Limitations	Baseline	6	7.6667	4.63321	2.744	0.041
	Follow up	6	2.3333	1.96638		
Overall QoL	Baseline	6	26.5000	10.80278	5.440	0.003
	Follow up	6	7.5000	7.89303		

There was a significant improvement in overall RQLQ scores in pediatric patients, however there was no significant improvement in 3 domains i.e nose symptoms, practical problems and other symptoms (tiredness, headache and irritability).

Table 3: Comparison of Rhinoconjuntivitis Quality of life Questionnaire (RQLQ) scores at baseline and follow up in adult patients.

RQLQ in Adults Domains	Intervention	N	Mean	SD	T	*P*
Sleep	Baseline	45	1.2896	1.143868	2.228	0.031
	Follow up	45	0.6815	1.16332		
Non-Hay fever symptoms	Baseline	45	0.6794	0.91582	2.142	0.038
	Follow up	45	0.3683	0.63413		
Practical problems	Baseline	45	1.1481	1.33249	3.413	0.001
	Follow up	45	0.5185	0.77053		
Nasal symptoms	Baseline	45	1.7333	1.49754	3.497	0.001
	Follow up	45	0.8056	0.99700		
Eye symptoms	Baseline	45	0.6056	0.93007	2.147	0.037
	Follow up	45	0.2833	0.42507		
Activities	Baseline	45	1.1926	1.33615	2.912	0.006
	Follow up	45	0.6000	0.76078		
Emotional	Baseline	45	0.4944	0.96308	1.957	0.057
	Follow up	45	0.2566	0.55772		
Overall QoL	Baseline	45	26.8000	24.91221	3.673	<0.001
	Follow up	45	13.3556	15.88984		

There was a significant improvement in RQLQ scores of adult patients at the end of the study.

Table 4: Comparison of Rhinoconjucntivitis Quality of life Questionnaire (RQLQ) scores at baseline and follow up in adolescent patients.

RQLQ scores in Adolescent Domains	Intervention	N	Mean	SD	T	P
Activities	Baseline	12	4.3611	1.05848	6.417	<0.001
	Follow up	12	2.1667	1.13262		
Practical Problems	Baseline	12	3.8000	0.95727	6.793	<0.001
	Follow up	12	2.1833	0.64079		
Non-Hay Fever symptoms	Baseline	12	2.7000	0.94772	7.030	<0.001
	Follow up	12	1.2167	0.83757		
Nasal symptoms	Baseline	12	2.3750	1.74675	3.403	0.006
	Follow up	12	0.5000	0.76871		
Eye symptoms	Baseline	12	0.8750	1.18944	1.711	0.115
	Follow up	12	0.3333	0.61546		
Emotional	Baseline	12	0.5625	0.65821	0.498	0.628
	Follow up	12	0.4167	0.82112		
Overall QoL	Baseline	12	14.6736	3.20822	8.913	<0.001
	Follow up	12	6.8167	2.28674		

There was a significant improvement in overall RQLQ scores of adolescent patients at the end of the study.

Table 5: Comparison of Dermatology Life Quality Index (DLQI) scores at baseline and follow up.

	Intervention	N	Mean	SD	T	P
DLQI Score	Baseline	16	4	3.7712	2.649	0.018
	Follow up	16	6.87	8.26136		

There was a significant improvement in DLQI scores in patients having skin complications at the end of the study.

Discussion

In a total of 70 patients, 46 patients (65.7%) were males and 24 patients (34.3%) were females. In our study males were predominant which was also observed in a study performed by Thomas Proctor et al. [9].

Our study results showed that most of the patients were sensitive to both Dermatophagoides pteronyssinus and Dermatophagoides farinae which was similar to the results of a study conducted by Beristain Ana et al. [10].

In our study, family history of allergy was found in 32.85% of the patients among which 5.7% of the patients had a family history of allergy in 1st and both 1st and 2nd degree relatives. 21.4% patients had a family history of allergies in 2nd degree relatives and 61.7% patients had no family history of allergies. Hence majority of the patients did not have a family history of allergies which was contradictory to the results of a study carried out by Moises A. Calderons et al. [11].

It can be seen from our study out of 70 patients, 5 (7.14%) patients were found to be smokers and 65 (92.8%) patients were found to be non-smokers which implied that smoking does not have any effect in causing House dust mite allergy. However, studied by Young Soo Kim et al [12] showed that smoking increases IgE levels which makes patients more prone to develop HDM allergy when exposed to Dermatophagoides farinae.

The mean age in our study group was found to be 28 + 13.65 years and majority of the patients were in the age group of 10-20 years which was similar to the results observed in a study performed by Beristain Ana et al. [10].

According to complaints of the patient, symptoms of HDM allergy were nasal (70%), eye (8%) and skin complications (22%) in which patients with nasal complications were found to be maximum, which was in correspondence to the results of a study conducted by Novakova et al. [13].

For statistical comparison of results, null hypothesis and alternative hypothesis were stated Null hypothesis patient counselling had no impact on Quality of Life of patients.

Alternative hypothesis patient counselling had a positive impact of Quality of Life of patients.

The results showed significant improvement in eye symptoms (p= 0.047), activity limitations (p= 0.041) and overall QoI (p=0.003). There was no significant improvement in the nasal symptoms, practical problems and other symptoms. These results were found to be contradictory to the results of a study carried out by Novakova et al [13] in which significant improvement in all domains of the Quality of Life was observed.

In adolescent patients, Quality of Life was assessed using adolescent Rhinoconjuntivitis Quality of Life Questionnaire which has 6 domains namely activity limitations, practical problems, non- hay fever symptoms, nasal symptoms, eye symptoms and emotional stability. Our study results showed significant improvement in activity limitation (p=<0.001), practical problems (p=<0.001), non-hay fever symptoms (p=<0.001), nasal symptoms (p=<0.006) and overall QoL (p=<0.001). Therefore, null hypothesis was rejected and alternative hypothesis was accepted. However, eye symptoms (p=0.115) and emotional stability (p=0.625) domains did not show a significant improvement following patient counselling. Hence, null hypothesis was accepted here and alternative hypothesis was rejected.

Quality of Life in adult patients was assessed using adult Rhinoconjuntivitis Quality of Life Questionnaire. The study results showed a significant improvement in all the 7 domains of the questionnaire namely sleep (p=0.031), non-hay fever symptoms (p=0.038), practical problems (p=0.001), nasal symptoms (p=0.001), eye symptoms (p= 0.037), activity limitations (p=0.006), emotional stability (p=0.057) and overall QoL (p=<0.001). Similar results were observed in a study performed by Fathima Ashkanani et al. [14].

In patients who had skin complications, QoL was assessed using the Dermatology Life Quality index (DLQI). Our study showed a significant improvement in DLQI scores (p=0.018) which was corresponding to the results of a study conducted by H.Kalboussi et al. [15].

During our study, no adverse reactions were observed following administration of SLIT therapy which was contradictory to the results of a study conducted by Novakova et al [13] which showed mild local, oral and GI reactions following SLIT therapy

In our study, 7 patients withdrew from the SLIT therapy due to the reason being delayed effect of SLIT, high therapy cost, long term use of medications and COVID19 pandemic. Similar observations were noted in a study conducted by Proctor et al. [9].

Conclusion

Patient counselling plays a major role in improving the health condition of patients suffering from chronic ailments and are on treatment with long term therapy.

Quality of life significantly improved in the adult's age group and adolescent age group after patient counselling.

During the study, no adverse reactions were observed following SLIT therapy.

Thus, it can be concluded that the intervention in the form of patient counselling had a positive impact on the quality of life in the adult patients.

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