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Quality of life improvement after sublingual immunotherapy for allergic rhinitis

Abstract

Background: Allergic rhinitis is a common disorder that is strongly affect patient quality of life. Subcutaneous allergen immunotherapy is showed to be an effective and safe treatment for allergic rhinitis; it is widely used in clinical practice, especially in European countries, since it is noninvasive, has minimal side-effects and can be easily administered at home

Objectives: To study the efficacy and safety of sublingual immunotherapy (SLIT) in the treatment of allergic rhinitisa using used the mini-rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) to assess the outcome.

Methods: A prospective study for 41 patients diagnosed with house dust mite (HDM) allergic rhinitis, who began sublingual immunotherapy (SLIT) during the period November 2014 to June 2016. All of patients were monosensitised to house dust mite as proved by skin prick test, the study was held in Otolaryngology Department, Hamad Medical Corporation, Doha, Qatar.

Results: The mean age is 35.2+/- 10.8. All patients have persistent moderate/severe allergic rhinitis and monsensitized to house dust mite. The major complaint of the patients before treatment was sneezing, stuffy blocked nose and the need to blow the nose. 83% of the patient scored >3 for sneezing, stuffy blocked nose, and need to blow nose repeatedly. The average Quality of Life (QoL) total score is 49.2+/-16.4. 76% of patients scored > 42. There is dramatic drop in the total score of symptoms from 49.19 +/- 16.39 pretreatment to 29.43 +/- 19.54 after treatment, the difference is statistically significant (p value<0.05).

Conclusion: Allergen immunotherapy with SLIT for house dust mite (HDM) allergy effectively reduces allergic rhinitis symptoms and the need for symptomatic medication in an adult population with moderate to severe allergic rhinitis.

Keywords: quality of life, allergic rhinitis, house dust mite, sublingual immunotherapy, slit, allergen immunotherapy

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Abbreviations: SLIT, sublingual immunotherapy; HDM, house dust mite; SCIT, subcutaneous immunotherapy; TGF, transforming growth factor; RCT, randomized controlled trial; IR, information retrieval

Introduction

Allergic rhinitis is an increasingly prevalent condition affecting about a quarter of the population in the developed world limiting the social life, school learning and work productivity.[1]

AR is a chronic disease showing symptoms of nasal congestion, nasal itching, rhinorrhea and sneezing[2]

Medical cost for AR treatment is increasing, and considering comorbid diseases including asthma, the treatment of AR has become more than just treating the rhinitis itself.[3] AR treatment can be classified into 4 categories: (1) avoidance and environmental control, (2) pharmacotherapy, (3) surgical treatment and (4) immunotherapy. Avoidance and environmental control is the safest way, but these are not always feasible. Intranasal corticosteroids and oral antihistamines have been accepted to be effective with few adverse effects. However, medical therapy only reduces allergic symptoms rather than reversing basic immunologic profiles of the AR patients. Surgical treatment is usually performed to correct structural problems which can aggravate nasal allergic symptoms and reduce the effective delivery of intranasal corticosteroids.[4–6]

One of the available causal treatments is allergen immunotherapy which is effective after the end of the treatment course, unlike symptomatic drugs. Specific immunotherapy (SIT) modifies the basic allergic mechanism of the disease by inducing desensitization through gradually increasing the dose of the specific allergen over an optimum long period.[7]

Traditionally, allergen-specific immunotherapy has been administered as subcutaneous injections. The sublingual approach has gained considerable interest as an alternative, and now several European countries use sublingual immunotherapy (SLIT) for the treatment of allergic respiratory diseases in preference to subcutaneous immunotherapy (SCIT) because of improved safety, easy administration and reduction of severe adverse reactions.

The first randomized controlled trial (RCT) worked on sublingual immunotherapy (SLIT) dates back to 1986.[2] In 2010, SLIT was included in the latest update of Allergic Rhinitis and its Impact on Asthma (ARIA) guideline for both adults and children.[8]

Today, SLIT is widely used in clinical practice, especially in European countries, since it is noninvasive, has minimal side-effects and can be easily administered at home. There are still some risks of adverse effects that range from mild local reactions like itching and swelling of the oral mucosa to severe systemic manifestation like anaphylaxis.[9]

Allergy to house dust mite (HDM) is the most common persistent respiratory allergy caused by inhalant allergens in Qatari population. We aim to discuss SLIT in the treatment of HDM induced AR in Qatari population, with a particular focus on efficacy and safety profile.

Materials and methods

Participants and recruitment

We ran a prospective study in our department for patients with dust mite allergic rhinitis were included in this study. All of them were monosensitised to house dust mite as proved by skin prick test, were enrolled consecutively in a case-control study. Recruitment took place between November 2014 to June 2016.

At inclusion the subjects had moderate to severe allergic rhinitis symptoms due to HDM despite frequent use of symptomatic medications such as antihistamines and nasal steroid spray ascertained during a 2week-baseline period and had never received immunotherapy previously. The cases were treated with specific house dust mite sublingual immunotherapy. 41 cases were actively treated and were included in the study.

Protocol

The medication (Stallergenes SAS, 6-rueAlexis deTocqucville, 92160 antony France) will be given using Sublingual route. Patient will start with the initial dose 10 IR/ML then conations on the maintenance dose 300 IR/ML.

The medication should be taken for 2 -3years continuously. The Drops of allergen extract must be kept under the tongue for 2min before being swallowed.

The first dose should be taken under the supervision of the doctor. After swallowing, the patient stays for 30minutes in the medical office under medical supervision for assessment.

The patient is instructed that the SLIT must be taken daily at the same time (in the morning in fasting conditions) and children will need the help of an adult when taking the medicine. The Follow-up is taking place every 3months during the first year, then every 4 months during the second year of treatment.

Outcome assessment

Studying the outcome and following up the symptomatic improvement of the patients using a questionnaire completed by the patient on his initial visit; before receiving the medication, as a baseline and on the time of the follow ups.

We used the mini-rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) (Table 1), to assess the outcome. The mini-RQLQ assesses QOL over the previous period. It is comprised of 14items, in five domains (Activity Limitations, Practical Problems, Nose Symptoms, Eye Symptoms and Other Symptoms), each evaluated on a seven point scale (0 = "Not troubled", 6 ="Extremely troubled"). The severity of nasal symptoms (itching, runny nose, sneezing, and nasal congestion) and ocular symptoms (itching, redness, and tearing) was scored according to the following scale: 0 = no symptoms; 1 = mild symptoms; 2 = moderate symptoms; 3 = severe symptoms, based on the patient's opinion.

The overall QoL total score is taken and compared to the previous visits. Considering a decrease in the total score is improvement in the symptoms. Safety assessments included adverse events reporting during each visit or by phone call.

Statistical analysis

Statistical analyses were performed using SPSS (SPSS, Chicago, IL, USA) software version 19. Descriptive statistics were performed expressing continuous data as means with SDs. Pre-treatment score was compared to post-treatment score. A p-value less than 0.05 were considered statistically significant.

Results

Clinicodemographic data

The mean age is 35.2+/- 10.8 There was slight male predominance in both groups (M/F= 21/20). All patients have persistent moderate/severe allergic rhinitis and monsensitized to house dust mite.

The major complaint of the patients before treatment was sneezing, stuffy blocked nose and the need to blow the nose. 83% of the patient scored >3 for sneezing, stuffy blocked nose, and need to blow nose repeatedly.

Table 2 shows the degree of improvement of symptoms and of quality of life 6months after treatment.

The average QoL total score is 49.2+/-16.4. 76% of patients scored > 42.

There is dramatic drop in the total score of symptoms from 49.19 +/- 16.39 pretreatment to 29.43 +/- 19.54 after treatment, the difference is statistically significant (p value<0.05).

There is also significant improvement in all pretreatment symptoms. The average score of sneezing dropped from 4.19 +/- 1.83to 2.56 +/- 2 , the average score for stuffy nose dropped from 4.29 +/- 1.9 to 2.67 +/- 2 , the average score for need to blow the nose dropped from 4.1 +/- 2.06 to2.34 +/- 1.9, the difference is statistically significant for all of them (P value <0.05) .

There were no anaphylactic reactions, severe systemic allergic reactions, adverse events requiring epinephrine, or local allergic reactions compromising the airways during the trial introduction. None of the patients reported any severe adverse event. There were no clinically relevant findings from physical examinations or vital signs.

Discussion

Allergen specific immunotherapy (SIT) has been studied and used for 1 century since Noon's first report in 1911.[4] SIT is the only treatment option that modified fundamental allergic mechanism by inducing desensitization. At first, SIT was used for allergic diseases caused by pollen allergen, such as hay fever or seasonal AR, however today, indications extends to hymenoptera venom, house dust mites (HDMs), animal dander and allergic diseases for fungi.[10]

ARIA 2008 suggested 4 main indications for SLIT: (1) patients with seasonal rhinitis "sensitive to pollens" or perennial rhinitis "sensitive to house mite"; (2) patients uncontrolled by pharmacological treatment; (3) patients presented by systemic reactions from the drugs; and (4) patients with poor compliance or refusing injections.[11]

SLIT is an allergen specific immunotherapy, which derive 3 major immunologic changes: (1) regulation of allergen specific antibody response, (2) reduction of proinflammatory cell recruitment and activation, and (3) changes in allergen specific T cell response.[12]

Mechanisms of SIT are not well identified till now. The most accepted theory is that SIT shifts the immune response from Th2

to Th1 through stimulation of the T-regulatory cell, which secretes interleukin (IL) and transforming growth factor (TGF)-β.[13] These T-regulatory cells with its mediators help to shift the immune response from the IgE to IgG. The IgG antibody especially IgG4 is considered as a blocking antibody which is known to interrupt the inflammatory cascade and stop the inflammatory mechanism initiated by the IgE release.[14]

Table 1 The mini-rhinoconjunctivitis Quality of Life Questionnaire (RQLQ)

	Not Troubled	Hardly Troubled at All	Somewhat Troubled	Moderately Troubled	Quite a Bit Troubled	Very Troubled	Extremely Troubled
Activities							
Regular activities at home and at work (your occupation or tasks that you have to do regularly around your home and/or garden)	0	1	2	3	4	5	6
Recreational activities (indoor and outdoor activities with friends and family, sports. social activities, hobbies)	0	1	2	3	4	5	6
Sleep (difficulties getting a good night's sleep and/or getting to sleep at night)	0	1	2	3	4	5	6
Practical Problems							
Need to rub nose/eyes	0	1	2	3	4	5	6
Need to blow nose repeatedly	0	1	2	3	4	5	6
Nose symptoms							
Sneering	0	1	2	3	4	5	6
Stuffy blocked nose	0	1	2	3	4	5	6
Runny nose	0	1	2	3	4	5	6
Eye Symptoms							
Itchy eyes	0	1	2	3	4	5	6
Sore eyes	0	1	2	3	4	5	6
Watery eyes	0	1	2	3	4	5	6
Other Symptoms							
Tiredness and/or fatigue	0	1	2	3	4	5	6
Thirst	0	1	2	3	4	5	6
Feeling irritable	0	1	2	3	4	5	6

Table 2 Outcome

QoL Criteria	Ave of QoL Score (0-6) before Treatment	Ave of QoL Score (0-6) after Treatment	P Value
Regular activities at home and at work	3.17+/-1.98	2.1 +/- 1.7	<0.05
Recreational activities	3.46 +/- 1.8	2.02 +/- 1.65	<0.05
Sleep	3.24 +/- 2.07	2.41 +/- 2.12	<0.05
Need to rub Nose or Eyes	3.09 +/- 1.85	2.24 +/- 1.81	<0.05
Need to blow Nose repeatedly	4.1 +/- 2.06	2.34 +/- 1.93	<0.05
Sneezing	4.19 +/- 1.83	2.56 +/- 2	<0.05
Stuffy Blocked Nose	4.29 +/- 1.9	2.67 +/- 2	<0.05
Runny Nose	3.26 +/- 1.93	1.63 +/- 1.71	<0.05
Itchy Eyes	2.97 +/- 1.89	2.12 +/- 1.92	<0.05
Sore EYES	2.75 +/- 2.03	1.24 +/- 1.68	<0.05
Watery Eyes	2.39 +/- 1.96	1.76 +/- 1.82	0.07
Tiredness	3.8 +/- 1.75	2.6 +/- 1.92	<0.05
Thirst	3.39 +/- 2.07	2.1 +/- 1.93	<0.05
Feeling Irritable	3.78 +/- 1.76	2.1 +/- 1.9	<0.05
Total Score	49.19 +/- 16.39	29.43 +/- 19.54	<0.05

The efficacy and safety of SLIT have been studied and in 2008, British Society for Allergy and Clinical Immunology announced SLIT as safe immunotherapy for AR and asthma.[15] Immunotherapy is generally considered more effective in monosensitised than polysensitised patients. Our study confirms the efficacy of SLIT in monosensitised patients.

Allergy to house dust mite (HDM) is the most common respiratory allergy caused by inhalant allergens and HDM allergic rhinitis is associated with an increased risk of developing asthma. A few studies have shown benefit of allergy immunotherapy in HDM allergy but there has been a need for more rigorous studies confirming the benefit.

In our studied group, already after 6months of treatment there was a significant improvement in the quality of life score. The subjects had fewer symptoms despite using less symptomatic medication to relieve their symptoms.

The results of our study confirm that the SLIT for HDM allergy effectively reduces allergic rhinitis symptoms and need for symptomatic medication in an adult population with moderate to severe allergic rhinitis. The results also showed that the HDM SLIT-tablet was well tolerated; supporting self-administration at home after the first tablet is taken under medical supervision.

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Conflicts of interest

Author declares there are no conflicts of interest.

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