



An Observational Study of Quality of Life in Patients of Allergic Rhinitis in a Tertiary Health Care Centre of South Gujarat

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Abstract Allergic rhinitis (AR) refers to an IgE-mediated inflammation following exposure to allergen. Often deemed as a minor inconvenience rather than a disease, AR impairs the QOL. Medical treatment has a beneficial effect. To evaluate the QOL in patients of AR. Patients of AR with ≥ 18 years age, receiving treatment in our department are included. Pre and Post treatment VAS (Visual Analogue Scale) and RSDI (Rhinosinusitis Disability Index) are compared to know the effect of disease and treatment on QOL. The patients of PAR (Persistent Allergic Rhinitis) had a greater impact on QOL. In PAR, a combination of INCS (Intranasal Corticosteroids) + oral antihistaminics result in significant reduction in VAS & RSDI scores. In IAR (Intermittent Allergic Rhinitis), Oral antihistaminics monotherapy was most effective in reducing itching while Oral antihistaminics + 1 week of intranasal decongestant was most effective in reducing sneezing, running nose and nasal blockage. Oral antihistaminics + LTRA (Leukotriene Receptor Antagonist) was most effective in reducing physical RSDI score. Oral antihistaminics + 1 week of intranasal decongestant was most effective in reducing functional and emotional RSDI score. Functional RSDI scores had improved much higher than emotional and physical scores. All these observations were statistically significant. AR does affect the QOL while pharmacotherapy helps in improving the overall QOL. Oral antihistaminic alone or in combination with local decongestant/LTRA in IAR cases while INCS + oral antihistaminic in

PAR cases are significantly effective in controlling symptom scores and QOL.

Keywords Allergic rhinitis · Quality of life · RSDI score · VAS score · Pharmacological treatment · ARIA guidelines

Introduction

Viennese Pediatrician Clemens Von priquet (1874–1929) introduced the term “Allergy” in 1906 [1]. The term “Allergy” is the combination of the Greek words ‘allos’ meaning different or changed, and ‘ergos’ meaning work or action [2]. Rhinitis is defined clinically by a combination of two or more nasal symptoms: running, blocking, itching and sneezing. Allergic rhinitis occurs when these symptoms are the result of IgE-mediated inflammation following exposure to allergen such as grass pollen, house dust mite, cat dander etc [3].

Often deemed as a minor inconvenience rather than a disease allergic rhinitis impairs the quality of life, mildly to severely [4, 5]. Patients commonly experience sleep disturbances, poor inter personal relationships with family and peers, mood swings, easy fatigability etc. Article QOL in allergic rhinitis This leads to decreased productivity at work and poor scholastic performances. Thereby a disease which has minimal treatment costs ends up putting a significant economic burden on the society due the non-medical losses which occur due to untreated disease [6, 7].

Allergic rhinitis is managed by allergen avoidance, pharmacotherapy and immunotherapy. Pharmacotherapy, according to ARIA Guidelines, includes antihistaminics, intranasal and oral steroids, decongestants, LTRA and chromones [3].

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Studies have proved that the pharmacologic treatment of AR has a beneficial effect on work productivity [8, 9].

One immeasurable result of any disease such as rhinosinusitis is the impact on quality of life. Recent efforts to evaluate the impact of disease on quality of life and the outcome of disease have clarified the importance of such impacts. Various QOL Questionnaires have been developed to assess the impact of allergic rhinitis on the quality of life and to determine the outcomes of treatment such as Rhinosinusitis Disability Index (RSDI), Chronic Sinusitis Survey (CSS), Sino Nasal Outcome Test (SNOT-22), Rhino conjunctivitis Quality of Life Questionnaire (RQLQ) etc. [10] Benninger et al., described that conventional methods for evaluating nasal-sinus disease are inadequate to assess the impact of these disorders on everyday life [11]. The RSDI is a 30-questioned instrument that measures the physical, functional and emotional impact of rhinosinusitis on a person's quality of life. Since the RSDI measures not only the physical symptoms but also the emotional and functional impact of the disorder, it can be seen that rhinosinusitis has a broader impact than that ascribed to the local symptoms alone [3].

Evaluating the effect of medical management on quality of life can provide an insight to health professionals in terms of expecting results upon starting pharmacological treatment.

On reviewing the literature, we found that almost no research has been done on QOL of patients of AR in this region of south Gujarat hence, we carried out this study to evaluate the QOL of AR patients and the impact of medical treatment on QOL.

Aims and Objectives

1. To measure the QOL (quality of life) of patients of AR by RSDI Score before receiving treatment.
2. To measure the effect of pharmacotherapy on QOL.

Methodology

This was an observational prospective study conducted in a tertiary health care centre of South Gujarat (Dept of ENT, Govt Med College & New Civil Hospital, Surat). Patients of AR (≥ 18 years age) receiving treatment between September 2019 and September 2020 were included. Convenient sampling method was used to collect the sample and related data.

In our department where most of the patients are migrant population and belongs to lower socioeconomic class AR is diagnosed clinically according to following case definition. Patients were considered to have AR if they presented with two or more of following nasal symptoms: running

nose (nasal discharge), nasal blockage, itching and sneezing with pale boggy nasal mucosa and after excluding ARS/CRS clinically.

Inclusion Criteria

1. Clinically diagnosed cases of AR.
2. Patients who had not taken anti-allergic medication for more than 6 weeks.
3. Patients with moderate to severe symptoms (according to ARIA guidelines).

Exclusion Criteria

1. Patients with rhinosinusitis other than AR.
2. Patients with sino-nasal tumours.
3. History of any nasal surgery.
4. Patients with mild symptoms (according to ARIA guidelines).
5. Patients with co morbidities like hypertension, diabetes mellitus, immune compromised states.
6. Patients who never came for any follow up visit.

Once patients were included in the study, they were given different drugs according to the ARIA guidelines (ARIA update recommendations 2008) [12].

38 patients were thus recruited in the study. Patients were asked to score their chief complaints viz itching, sneezing, nasal discharge and nasal blockage (individually for all 4 symptoms) as per the Visual Analogue Scale (VAS) in the form of Numerical Rating Scale from 0 to 10 as per the severity of symptom, where 0 means "no symptom" and 10 means "worst possible symptom". For evaluation of response of treatment, the symptoms were classified as mild (VAS = 1–3), moderate (VAS = 4–7) and severe (VAS = 8–10). They were also explained the questions of RSDI Questionnaire and the response were evaluated individually for each question. Participants were asked to come for follow-up visits at 2 weeks post treatment to evaluate the responses again by VAS and RSDI score.

The collected data was entered in a spreadsheet (Excel, Microsoft Office 2019) and statistically evaluated using R statistical software version 4.0.2. Paired t-test was applied to detect statistical significance of changes in VAS and RSDI scores pre and post treatment and thereby evaluating the effect of various drug/s on the QOL. The SRM (standardized response mean) was also measured which is useful in gauging the responsiveness of scales (VAS and RSDI) to clinical change. Hence a greater SRM indicates better responsiveness for the given drug/s.

Results

We found that 39.5% patients who were using preventive measures had average RSDI score 76.12 as compared to 78.87% RSDI score in those 60.5% patients who were not using preventive measures. Which means that QOL is affected less severely in those who uses protective measures.

We found in our study that out of total 38 patients, 44.7% (17 cases) had PAR and rest 55.3% (21 cases) had IAR.

Cases of mild AR are excluded from the study. Amongst moderate-Severe cases, the patients of PAR had a greater pre-treatment RSDI score (78.76) as compared to IAR (69.74). Which means PAR affect the QOL severely then IAR.

In our dept pharmacotherapy is started based on ARIA guidelines. Choice of molecule of drug and brand depend upon the availability in the institute/affordability of patients/ tolerance.

All patients of PAR (44.7%) were given combination of INCS + oral antihistaminics. In cases of IAR (55.3%) three different combinations were used as follows: Oral antihistaminics monotherapy in 34.21% (13), Oral antihistaminics + 1 week of intranasal decongestant in 15.78% (6) and Oral antihistaminics + LTRA in 5.26% (2).

In the patients of moderate-severe PAR, after 2 weeks of pharmacotherapy with INCS + oral antihistaminics we observed reduction in VAS for individual symptoms as seen in Table 1.

Patients of IAR in this this study has received three different combinations of drug/s as per ARIA. While

analysing the most effective drug/s for individual symptoms in the patients of IAR, we observed that Oral antihistaminic + 1 week of Intranasal decongestant was most effective in reducing Sneezing, Running nose and Nasal blockage while for Itching Oral antihistaminic monotherapy was most effective. Observed reduction in VAS for most effective drug/s against individual symptoms is as shown in Table 2.

In this study the QOL was assessed by RSDI score which other then Total score also includes other domains like physical, functional end emotional scores. In our study, after 2 weeks of pharmacotherapy 94.7% patients showed improvement in RSDI scores while 5.26% showed deterioration.

Following analysis exclude those 5.26% cases who showed deterioration in the RSDI score.

In both PAR and IAR, all domains (Total, Physical, Functional and Emotional) of RSDI were reduced and were statistically significant. In patients of PAR, after 2 weeks of pharmacotherapy with INCS + oral antihistaminics we observed reduction in RSDI score as seen in Table 3.

In the patients of IAR, most effective drug/s for individual form of RSDI is as shown in Table 4.

Functional RSDI scores (SRM = 1.39) have improved much higher than physical (SRM = 1.09) and emotional (SRM = 1.03) after 2 weeks of pharmacotherapy.

Table 1 Pharmacotherapy of PAR and its effect on symptoms (VAS score)

Symptom	Observed reduction in VAS score (mean ± SE) 2 weeks post treatment	Standardized response mean (SRM)	P value	Statistically significant
Itching	1.24 ± 1.27	0.48	0.07	No
Sneezing	3.35 ± 3.43	1.18	0.0002	Yes
Running nose	2.71 ± 2.84	0.92	0.002	Yes
Nasal blockage	1.65 ± 1.48	0.81	0.004	Yes

Table 2 Pharmacotherapy of IAR and its effect on symptoms (VAS score)

Symptom	Most effective drug	Observed reduction in VAS score (mean ± SE) 2 weeks post treatment	Standardized response mean (SRM)	P value	Statistically significant
Itching	Oral antihistaminics monotherapy	2.31 ± 2.45	1.05	0.003	Yes
Sneezing	Oral antihistaminics + 1 week of intranasal decongestant	3.5 ± 3.07	1.39	0.02	Yes
Running Nose	Oral antihistaminics + 1 week of intranasal decongestant	3.83 ± 4.18	1.50	0.01	Yes
Nasal Blockage	Oral antihistaminics + 1 week of intranasal decongestant	3.5 ± 3.26	1.32	0.02	Yes

Table 3 Pharmacotherapy of PAR and its effect on QOL (RSDI Score)

Symptom	Observed reduction in RSDI score (mean \pm SE) 2 weeks post treatment	Standardized response mean (SRM)	P value	Statistically significant
Total	20.7 \pm 19.79	1.01	0.0007	Yes
Physical	6.82 \pm 7.64	0.87	0.003	Yes
Functional	8.18 \pm 7.86	1.26	0.00009	Yes
Emotional	5.71 \pm 5.29	0.79	0.005	Yes

Table 4 Pharmacotherapy of IAR and its effect on QOL (RSDI Score)

Symptom	Most effective drug	Observed reduction in RSDI score (mean \pm SE) 2 weeks post treatment	Standardized response mean (SRM)	P value	Statistically significant
Total	Oral antihistaminics + 1 week of intranasal decongestant	26.2 \pm 9.90	2.18	0.003	Yes
Physical	Oral antihistaminics + LTRA	6.5 \pm 6.43	9.29	0.05	Yes
Functional	Oral antihistaminics + 1 week of intranasal decongestant	10.3 \pm 11.24	2.24	0.003	Yes
Emotional	Oral antihistaminics + 1 week of intranasal decongestant	9.67 \pm 9.37	2.11	0.004	Yes

Discussion

In sensitized symptomatic individuals, allergen avoidance is desirable and should be regarded as complementary to usual pharmacotherapy with antihistamines and topical intranasal corticosteroids. However, allergen avoidance measures are frequently expensive, time-consuming and impracticable [3].

In our study population, 39.5% patients who were using protective measures had average RSDI score slightly lower viz. 76.12 as compared to 78.87 in non-users. In a study done by A.A Dror et al., the proportion of nurses (20.5%) reporting severe overall symptom burden decreased significantly after wearing a surgical mask (13.0%; $p=0.0388$) or an N95 respirator (12.6%; $p=0.0272$) as compared with no mask, thereby highlighting the potential benefits of wearing mask [13]. However, because of the small sample size and the lower RSDI score not being statistically significant, we cannot conclude the same in this study.

The patients of PAR were given a combination of INCS + oral antihistaminics. After 2 weeks, average VAS score for itching had reduced though it was not statistically significant. Whereas the average VAS score for sneezing, running nose & nasal blockage had reduced significantly. N. Juel-Berg et al. had also concluded that intranasal steroids helped in relieving nasal itching, sneezing, nasal discharge and nose block [10]. The total RSDI score had reduced which was statistically significant. All the domains i.e., the physical, functional and emotional RSDI score reduced significantly. Potter et al. found that improvements in the mean

scores of the RQLQ were significantly better with triamcinolone as compared with placebo [9].

The patients of IAR were given three different drug/s (oral antihistaminics monotherapy, oral antihistaminics + 1 week of intranasal decongestant and Oral antihistaminic + LTRA). Oral antihistaminics monotherapy was most effective in reducing itching significantly. While, oral antihistaminics + 1 week of intranasal decongestant was most effective in reducing sneezing, running nose and nasal blockage significantly. Stübner et al. found that subjective symptoms were significantly better under Cetirizine/Pseudoephedrine as compared to topical Xylometazoline [14]. Barnes et al. reported that Xylometazoline effects were greater than Mometasone furoate ($p < 0.05$) in patients of AR [15].

Oral antihistaminics + 1 week of intranasal decongestant was most effective in reducing total as well as emotional and functional RSDI score significantly. Oral antihistaminics + LTRA was most effective in reducing physical RSDI score. Lu yi et al. concluded that Montelukast reduced RQLQ (rhino conjunctivitis quality of life questionnaire) scores in patients with IAR and PAR and it was statistically significant, when compared with placebo [16]. Meltzer et al. reported that once-daily Fexofenadine HCl significantly improved patient-reported quality of life and reduced performance impairment in work and daily activities due to seasonal allergic rhinitis symptoms compared with placebo [17].

All p -values were less than 0.05 at 95% CI indicating that improvements in RSDI score is statistically significant.

SRM values are over 0.5 signifying that RSDI scores are responsive to health status in total as well as in subscales. Functional RSDI scores (SRM = 1.39) have improved much higher than physical (SRM = 1.09) and emotional (SRM = 1.03) after 2 weeks of pharmacotherapy.

In our study, 94.7% patients showed improvement in RSDI scores. While, H. Chen et al. had found that RSDI scores improved by 0.5 standardized response mean in 19% subjects [18]. The patients of PAR had a greater impact on their QOL as a result of their disease, as seen by a greater RSDI score (78.76) as compared to patients of IAR (RSDI score = 69.74). R.N Kalmarzi et al. found that the quality of life was reduced significantly in patients with severe IAR allergic rhinitis ($p < 0.05$) 0.4

Conclusion

The patients of moderate- severe PAR had a greater reduced QOL as compared to the patients of moderate- severe IAR. Protective measures improved the QOL of AR patients, hence allergen avoidance should be attempted by sensitised individuals.

In the patients of moderate-severe IAR, oral antihistaminics monotherapy was most effective in reducing itching. While, oral antihistaminics + 1 week of intranasal decongestant was most effective in reducing sneezing, running nose & nasal blockage significantly.

Combination therapy with INCS + oral antihistaminics for 2 weeks resulted in reduction of total RSDI score in the patients of moderate-severe PAR. This indicates that there was a significant improvement in physical, functional and emotional disability quotient of the patients. Whereas, in the patients of moderate-severe IAR, maximum improvement in QOL was seen with oral antihistaminics + 1 week of intranasal decongestant, especially in the functional and emotional domains. These improvements were statistically significant. Functional RSDI scores had improved much higher than physical and emotional scores after 2 weeks of pharmacotherapy. So, we can expect a return to normal day to day functions after a couple of weeks of starting treatment.

We can conclude that pharmacotherapy helps in improving the overall QOL and symptoms in patients of AR.

Limitations of the Study

The unprecedented COVID-19 pandemic had resulted in complete cessation of routine as well as emergency clinical work for 6 months in our institute. This was the most important reason for smaller than expected sample size. Originally, we planned to do follow up at 2nd and

4th week. But 4th week follow up didn't become possible due to covid outbreak

Sample size is small hence results cannot be generalised. We have diagnosed AR on the basis of clinical signs and symptoms. Some of our participants might have had other types of non-allergic rhinitis like NARES which mimic AR symptomatically.

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