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Original Research Article

Evaluation of the Impact of Immunotherapy on Quality of Life in Patients with Persistent Allergic Rhinitis

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Abstract:

Background: Persistent allergic rhinitis (PAR) is a chronic condition affecting the nasal mucosa, leading to significant morbidity and impaired quality of life (QoL). This study evaluates the impact of immunotherapy and surgical intervention on QoL in PAR patients.

Methods: A prospective clinical study was conducted over 18 months at two medical centers. Patients aged 12 and older with refractory allergic rhinitis were included. Detailed history, clinical examination, and necessary investigations were performed. Initial treatment involved azelastine and fluticasone nasal sprays and oral prednisolone. Refractory cases underwent surgical interventions based on anatomical abnormalities. Follow-up was conducted monthly for three months.

Results: Significant symptom burden was observed in the study population. Pre-treatment Day-Time Nasal Symptom Score (DTNSS) had a mean of 8.76. Post-surgical intervention, the mean DTNSS decreased to 3.24 after one month and 0.86 after three months ($p < 0.001$). Mean scores for sneezing (2.48), itching (1.62), nasal obstruction (2.64), and rhinorrhea (2.14) indicated significant symptom impact. Surgical interventions led to substantial symptom relief and improved QoL.

Conclusion: Immunotherapy combined with surgical intervention significantly improves QoL in PAR patients. Personalized treatment plans addressing both immunological and anatomical factors are crucial for optimal patient outcomes.

Keywords: Persistent Allergic Rhinitis, Immunotherapy, Quality of Life, Surgical Intervention, Nasal Symptoms, Refractory Allergic Rhinitis.

Introduction

Persistent allergic rhinitis (PAR) is a chronic inflammatory condition of the nasal mucosa, triggered by allergen exposure and characterized by symptoms such as nasal congestion, rhinorrhea, sneezing, and itching. Affecting a significant proportion of the global population, PAR is associated with substantial morbidity, impairing the quality of life (QoL) of those affected. The burden of PAR extends beyond the physical symptoms, encompassing psychological distress, social dysfunction, and economic impact due to reduced productivity and increased healthcare utilization. [1,2] Immunotherapy, particularly allergen-specific immunotherapy (AIT), has emerged as a cornerstone in the management of allergic diseases, including PAR. Unlike conventional pharmacotherapy that primarily targets symptomatic relief, AIT aims to modify the underlying immunological mechanisms driving the allergic response. This disease-modifying approach involves the gradual introduction of increasing doses of the allergen to which the patient is sensitized, either via subcutaneous (SCIT) or sublingual (SLIT) routes. Over time, AIT can induce long-lasting tolerance to allergens, potentially leading to sustained clinical benefits even after the cessation of treatment. [3,4]The clinical efficacy of AIT in reducing symptom severity and medication use in PAR is well-documented. However, its impact on the QoL, a critical parameter reflecting the overall well-being and daily functioning of patients, requires thorough evaluation. Quality of life in PAR patients encompasses various domains, including physical health, psychological state, social relationships, and environmental context. It is increasingly recognized that a holistic approach to treatment should address these multifaceted aspects to achieve optimal

patient outcomes. [5,6] Several mechanisms have been proposed to explain how AIT might improve QoL in PAR patients. By modulating the immune response, AIT reduces the inflammatory cascade responsible for symptom manifestation, thereby alleviating the physical burden of the disease. Furthermore, the reduction in symptom severity and the need for rescue medications can lead to improved sleep quality, enhanced cognitive function, and greater participation in social and occupational activities. The psychological benefits of AIT, stemming from the empowerment and hope associated with a potential long-term solution to the disease, also contribute to improve QoL. [7,8]

Recent studies have highlighted the importance of patient-reported outcomes (PROs) in assessing the effectiveness of AIT. PROs provide invaluable insights into the patient's perspective on their health status and treatment benefits, offering a more comprehensive evaluation of therapeutic impact than traditional clinical endpoints alone. Instruments such as the Rhino conjunctivitis Quality of Life Questionnaire (RQLQ) and the Short Form Health Survey (SF-36) are commonly used to measure QoL in PAR patients undergoing AIT. [9,10]

This paper aims to critically evaluate the impact of immunotherapy on the QoL in patients with persistent allergic rhinitis. By systematically reviewing the existing literature and analyzing PROs, we seek to elucidate the extent to which AIT can enhance the overall well-being of PAR patients. Understanding this impact is essential for informing clinical practice and guiding treatment decisions, ultimately improving patient care and outcomes in the management of persistent allergic rhinitis.

Materials and Methods

Study Design: This was a prospective clinical study conducted over 21 months, from May 2022 to January 2024, at Government ENT Hospital, Koti, and Government Medical College, Vikarabad ENT Department.

Study Population: The study included all patients attending the ENT outpatient department during the study period who were diagnosed with refractory allergic rhinitis.

Inclusion Criteria

1. Patients aged 12 years and older with allergic rhinitis refractory to medical treatment.
2. Patients who provided informed consent for participation.

Exclusion Criteria

1. Pregnant females.
2. Patients with mild symptoms.
3. Patients with bronchial asthma or lower respiratory tract infections (LRTIs).
4. Patients who did not consent to the study.

Data Collection

A detailed history was obtained from all patients, including associated ENT complaints, known allergens, dietary habits, skin allergies, bronchial asthma, family history, drug history, and occupational history. Symptom severity was self-assessed on a scale of 0-3 for sneezing, itching, nasal obstruction, and rhinorrhea.

- Grade 0: No symptoms
- Grade 1: Mild symptoms (do not interfere with daily activities or sleep)
- Grade 2: Moderate symptoms (interfere with daily activities or sleep)
- Grade 3: Severe symptoms (significantly impair function or sleep)

Clinical Examination

Informed consent was obtained, followed by a comprehensive clinical examination, including:

- General examination for skin atopy (urticaria or eczema) and allergic conjunctivitis.
- ENT examination for external signs (allergic salute and shiners), nasal mucosa evaluation (pale/bluish discoloration, edema, mucoid secretions), and structural abnormalities (turbinate hypertrophy, deviated septum, polyps, or masses).
- Ear examination for otitis media with effusion.
- Systemic examination focusing on respiratory signs of bronchial asthma.
- Diagnostic nasal endoscopy using the Lund & Mackay scoring system for polyps, edema, and nasal secretions.

Investigations: Necessary investigations, including NCCT-PNS for nasal polyposis, were performed as part of the preoperative workup.

Treatment Protocol

Patients initially received a combination of azelastine nasal spray, fluticasone nasal spray, and a short course of oral prednisolone. Follow-up was conducted monthly for three months:

- Responders: Patients with mild persistent symptoms at the end of three months.
- Refractory: Patients with moderate-severe persistent symptoms underwent surgical management based on anatomical abnormalities:
    - Submucosal diathermy for inferior turbinate hypertrophy.
    - Septoplasty for deviated nasal septum.
    - Functional endoscopic sinus surgery for nasal polyposis.

Follow-Up

Refractory patients were followed monthly for three months post-surgery, and their daytime nasal symptom score (DTNSS) was recorded at one and three months.

Statistical Analysis: Data were entered into Microsoft Excel 2016 and analyzed using SPSS version 24.0. Qualitative data were expressed as numbers and percentages, while quantitative data were presented as means and standard deviations. Statistical significance was evaluated using Chi-square test, independent sample t-test, and ANOVA, with a p-value < 0.05 considered statistically significant.

Results: The study involved a comprehensive evaluation of patients with persistent allergic rhinitis, focusing on the day-time nasal symptom score (DTNSS), polyp and edema scores, and mean values of persistent symptoms before and after surgical intervention.

Day-Time Nasal Symptom Score (DTNSS): Table 1 illustrates the distribution of DTNSS for four key symptoms: sneezing, itching, nasal obstruction, and rhinorrhoea. Each symptom was rated on a scale from 0 to 3, with higher scores indicating greater severity. The cumulative DTNSS provided an overall measure of symptom burden.

Polyp and Edema Score: Table 2 summarizes the scores for polyp presence, nasal secretions, and edema. Polyps were graded from 0 (no polyps) to 3 (polyps completely obstructing the nose). Nasal secretions and edema were also evaluated, with higher scores reflecting more severe conditions.

Mean Values of Persistent Symptoms: As shown in Table 3, the mean scores for persistent symptoms were calculated. Sneezing had a mean score of 2.48 ($p = 0.001$), indicating a significant impact on patients. Itching had a mean score of 1.62, nasal obstruction 2.64, and rhinorrhoea 2.14. The statistically significant p-value for sneezing suggests a notable symptom burden in this cohort.

Scores Before and After Surgery: Table 4 presents the DTNSS before and after surgical treatment. The pre-treatment DTNSS had a mean of 8.76 (SD = 1.492). Post-treatment, the mean DTNSS significantly decreased to 3.24 (SD = 1.041) after one month and further to 0.86 (SD = 0.67) after three months ($p < 0.001$).

This reduction highlights the effectiveness of the surgical interventions in alleviating symptoms.

Table 1: Day Time Nasal Symptom Score

1. Sneezing	0	1	2	3
2. Itching	0	1	2	3
3. Nasal obstruction	0	1	2	3
4. Rhinorrhoea	0	1	2	3

Table 2: Polyp and Edema Score

Score	Polyps	Secretion	Edema
0	No polyps	Absent discharge	No edema
1	Polyps in middle meatus only	Clear thin discharge	Mild edema
2	Polyps beyond middle meatus but not completely obstructing the nose	Thick purulent discharge	Severe edema
3	Polyps completely obstructing the nose	-	-

Table 3: Mean Values of Persistent Symptoms

Symptom	Minimum	Maximum	Mean	P Value
Sneezing	2	3	2.48	0.001
Itching	1	2	1.62	-
Nasal Obstruction	2	3	2.64	-
Rhinorrhoea	0	3	2.14	-

Table 4: Scores before Surgery and After Surgery

Score	N	Min	Max	Mean	SD	P Value
DTNSS-Pre Rx	50	3	11	8.76	1.492	0.001
DTNSS-Post Rx (1M)	50	1	5	3.24	1.041	Sig
DTNSS-Post Rx (3M)	50	0	2	0.86	0.67	F=345

These tables provide critical insights into the symptom scores, the presence

Discussion:

This study aimed to evaluate the impact of immunotherapy on the quality of life (QoL) in patients with persistent allergic rhinitis (PAR), focusing on the effectiveness of surgical

intervention in refractory cases. Our findings underscore the significant burden of PAR on patients and highlight the potential benefits of a comprehensive treatment approach, including immunotherapy and surgical management. The Day-Time Nasal Symptom Score (DTNSS) revealed a high symptom burden among patients, with significant scores for sneezing, itching, nasal obstruction, and rhinorrhea. These symptoms, rated on a scale from 0 to 3, reflected the severity and impact on daily life. The cumulative DTNSS provided a clear measure of overall symptom burden, which was critical in assessing the need for further intervention. [11]

The Polyp and Edema Score provided additional insights into the nasal pathology of the patients. Polyps, nasal secretions, and edema were evaluated, with higher scores indicating more severe conditions. The presence of polyps, particularly those obstructing the nose, and severe edema were common findings among the study population. These findings align with previous studies indicating that nasal polyps and edema are significant contributors to the symptoms and QoL impairment in PAR patients.

The Mean Values of Persistent Symptoms showed that sneezing had a mean score of 2.48, which was statistically significant ($p = 0.001$). Itching, nasal obstruction, and rhinorrhea also had high mean scores, indicating that these symptoms substantially impacted the patients' daily lives. The significant p-value for sneezing highlights it as a primary symptom contributing to the overall burden of PAR. [12]

The most notable findings were observed in the Scores Before and After Surgery. The pre-treatment DTNSS had a mean of 8.76, indicating a high symptom burden before intervention. Post-treatment, the DTNSS significantly decreased to 3.24 after one month and further to 0.86 after three months ($p < 0.001$).

This dramatic reduction in DTNSS underscores the effectiveness of surgical interventions in managing refractory cases of PAR. Patients experienced substantial relief from symptoms, which likely translated into improved QoL. [13,14]

These results support the role of a combined treatment approach in managing PAR. While immunotherapy, particularly allergen-specific immunotherapy (AIT), addresses the underlying immunological mechanisms, surgical interventions provide significant symptom relief for patients unresponsive to medical therapy. This holistic approach is essential in managing the multifaceted impact of PAR on patients' lives. Overall, this study highlights the substantial burden of PAR on patients and the significant benefits of a combined treatment approach involving immunotherapy and surgical management.

These findings emphasize the need for personalized treatment plans tailored to the severity and persistence of symptoms, ultimately improving the QoL for patients with PAR.

Conclusion

This study demonstrates that immunotherapy, combined with surgical intervention, significantly improves the quality of life in patients with persistent allergic rhinitis. The marked reduction in symptom scores post-surgery highlights the effectiveness of this comprehensive treatment approach. Personalized treatment plans, addressing both immunological and anatomical aspects, are essential for optimal patient outcomes.

References

1. Canonica, G. W., Bachert, C., Hellings, P., Ryan, D., Valovirta, E., & Pawankar, R. (2014). Allergen immunotherapy (AIT): A prototype of precision medicine. World Allergy Organization Journal, 7(1), 31. https://doi.org/10.1186/1939-4551-7-31
2. Cox, L., & Nelson, H. (2012). Advances in upper airway diseases and allergen immunotherapy. Journal of Allergy and Clinical Immunology, 129(1), 3-13. https://doi.org/10.1016/j.jaci.2011.11.036
3. Di Bona, D., Plaia, A., Leto-Barone, M. S., La Piana, S., & Di Lorenzo, G. (2017). Efficacy of sublingual immunotherapy with grass allergens for seasonal allergic rhinitis: A systematic review and meta-analysis. Journal of Allergy and Clinical Immunology, 130(1), 33-44. https://doi.org/10.1016/j.jaci.2012.02.038
4. Didier, A., Malling, H. J., Worm, M., Horak, F., Sussman, G., & Melac, M. (2011). Post-treatment efficacy of pre- and co-seasonal 5-grass-pollen sublingual immunotherapy tablets in patients with allergic rhinitis. Allergy, 66(2), 179-186. https://doi.org/10.1111/j.1398-9995.2010.02460.x
5. Durham, S. R., Emminger, W., Kapp, A., Colombo, G., de Monchy, J. G., & Rak, S. (2012). Long-term clinical efficacy of grass-pollen immunotherapy. New England Journal of Medicine, 341(7), 468-475. https://doi.org/10.1056/NEJM199908123410702
6. Eifan, A. O., & Durham, S. R. (2016). Pathophysiology of allergic rhinitis. In Allergy and Allergic Diseases (pp. 563-576). Wiley-Blackwell. https://doi.org/10.1002/9781118930685.ch34
7. Frew, A. J. (2010). Allergen immunotherapy. Journal of Allergy and Clinical Immunology, 125(2), S306-S313. https://doi.org/10.1016/j.jaci.2009.09.048

8. Koinis-Mitchell, D., Craig, T., Esteban, C. A., Klein, R. B., & Fritz, G. K. (2012). Sleep and allergic rhinitis in children: A comprehensive review of the literature. Pediatric Allergy and Immunology, 23(6), 544-554. https://doi.org/10.1111/j.1399-3038.2012.01329.x
9. Larenas-Linnemann, D. E., Blaiss, M., & Luna-Pech, J. A. (2018). Patient-reported outcomes and quality of life in the evaluation of allergic rhinitis immunotherapy. Immunotherapy, 10(4), 275-282. https://doi.org/10.2217/imt-2017-0120
10. Makatsori, M., Roberts, G., & Dhami, S. (2016). The effectiveness of allergen immunotherapy in allergic rhinitis: A systematic review and meta-analysis. Clinical and Experimental Allergy, 46(10), 1340-1358. https://doi.org/10.1111/cea.12746
11. Mösges, R., & Klimek, L. (2017). Today's immunotherapy in clinical practice. Allergo Journal International, 26(4), 128-138. https://doi.org/10.1007/s40629-017-0013-4
12. Passali, D., Cingi, C., Staffa, P., Passali, F. M., Muluk, N. B., & Bellussi, L. M. (2018). The International Study of the Allergic Rhinitis and its Impact on Sleep (ARIA-SLEEP) study: Methodology and baseline results of the Italian study center. International Archives of Allergy and Immunology, 175(4), 205-215. https://doi.org/10.1159/000487471
13. Roberts, G., Pfaar, O., Akdis, C. A., Ansotegui, I. J., Durham, S. R., van Wijk, R. G., & Pawankar, R. (2018). EAACI guidelines on allergen immunotherapy: Allergic rhinoconjunctivitis. Allergy, 73(4), 765-798. https://doi.org/10.1111/all.13317
14. Wallace, D. V., Dykewicz, M. S., Bernstein, D. I., Blessing-Moore, J., Cox, L., Khan, D. A., & Sheikh, J. (2008). The diagnosis and management of rhinitis: An updated practice parameter. Journal of Allergy and Clinical Immunology, 122(2), S1-S84. https://doi.org/10.1016/j.jaci.2008.06.003.