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Impact of surgery and intranasal corticosteroid therapy on quality of life of patients with allergic rhinitis

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Abstract

Introduction: Prevalence of allergic rhinitis (AR) in India ranges from 10% to 15%. AR significantly affects the quality of life (QOL). This study was designed with an objective to assess the impact of surgery and 3 months of intranasal corticosteroids therapy on the QOL of patients with AR. **Materials and Methods:** A before and after comparison cross-sectional study was conducted between April 2012 and December 2013. A total of fifty consecutive patients in the age group of 19-59 years suffering from moderate-severe AR presenting at KKR ENT Hospital and Research Institute were included in the study after taking their consent. Individuals with contraindications for the surgery or intranasal corticosteroid therapy were excluded from the study. QOL was assessed using the mini rhinoconjunctivitis QOL questionnaire before the surgery and 3 months after starting corticosteroid therapy following the surgery. The study was approved by the Institutional Ethical and Scientific Committee. Absolute eosinophil count (AEC) and QOL scores were used to measure the impact. Descriptive statistics and paired *t*-tests were used to analyze the data and lend statistical support. **Results:** Mean AEC reduced from 517.66 (± 74.42) to 322.70 (± 54.68) after surgery and 3 months of intranasal corticosteroid therapy, and this reduction was statistically significant ($P < 0.001$). Mean QOL scores reduced from 2.624 (± 0.445) to 2.031 (± 0.386) after surgery and 3 months of intranasal corticosteroid therapy, and this reduction was statistically significant ($P < 0.001$). **Conclusions:** Within 3 months after the surgery and intranasal corticosteroid therapy, the mean AEC as well as the mean QOL scores reduced significantly indicating a reduction in the allergic reaction and an improvement in the QOL of patients suffering from AR.

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Full Text

INTRODUCTION

Rhinitis is defined as an inflammation of the membranes lining the nose and is characterized by one or more of the following symptoms: Nasal congestion, rhinorrhea, sneezing, itching of the nose and/or postnasal drainage, throat clearing, headaches, facial pain, ear pain, itchy throat and palate, snoring, and sleep disturbances. [1],[2],[3] When symptoms of rhinitis are triggered by an allergen, the resulting condition is referred to as allergic rhinitis (AR). In such patients, there is evidence of concomitant allergic disease, determined by a positive skin prick test for relevant allergens and/or positive allergen-specific antibody tests. [4] It is classified on the basis of duration of symptoms as "persistent AR" and "intermittent AR" along with the severity of symptoms as "mild" or "moderate-severe." [5],[6]

AR is a major chronic respiratory disease due to its high prevalence, definite impact on quality of life (QOL), definite impact on work/school performance and productivity, high economic burden, and strong links with asthma. [7]

AR is a very common condition throughout the world. [8] Using a conservative estimate, AR occurs in over 500 million people around the world. [7] In the Western countries, the prevalence of AR among all age groups varies from 10% to 40%. [9] In India, studies have reported a prevalence ranging from 10% to 15% for AR. [10] Overall, the prevalence has increased over the recent decade probably due to changes in lifestyle, industrialization, and increase in air pollution. [10]

Globally, AR is a cause of significant and widespread morbidity in all age groups. [11] There is evidence to prove that AR significantly impairs the QOL of the patient by causing fatigue, headache, cognitive impairment, and other associated symptoms. [12],[13],[14],[15],[16],[17],[18],[19] In addition, AR and other allergic diseases have a progressive nature, and allergic sensitization increases the risk of developing systematic diseases. [20],[21]

However, AR is rather erroneously viewed as a trivial disease, [22] and consequently it does not get the attention that it deserves by both patients as well as clinicians, especially in developing countries like India. [23] Current therapeutic modalities for the management of AR include avoidance of allergens, intranasal corticosteroids, oral or topical H1 receptor antagonists, mast-cell stabilizers, leukotriene receptor antagonists, anticholinergic agents in oral or topical nasal formulations, immunotherapy, and surgery. [4],[11] But usually, a combination of multiple modalities of therapy has to be used judiciously to manage AR since any one single method is not completely effective. Intranasal corticosteroid therapy is one of the most effective treatment modality available for rhinitis, [24] especially if started before allergen exposure. Surgical therapy also has a role to play in AR, usually as an adjunctive therapy to either intranasal corticosteroids or immunotherapy. [6] Surgery for AR essentially involves reduction in the size of the inferior turbinate.

Despite many studies done on the impact of different treatments on AR in the Western population, there are not many studies done in the Indian population. Hence, we designed this study with an objective to assess the impact of surgery and intranasal corticosteroids therapy on the QOL of patients with AR.

MATERIALS AND METHODS

A cross-sectional study (before and after comparison) was conducted from April 2012 to December 2013 at KKR ENT Hospital and Research Institute. Using the prevalence of 15%, [10] the sample size for this study was estimated to be 48.96 (using the formula, $n = Z^2pq/d^2$; where $d = 10\%$, $\alpha = 5\%$, $\beta = 80\%$). A total of fifty consecutive patients in the age group of 19-59 years suffering from clinical signs and symptoms of moderate-severe AR presenting to the outpatient department were included in the study provided they consented to undergo surgery, to take intranasal corticosteroid therapy for 3 months, and to come for follow-up after 3 months. Individuals with contraindications for the surgery or intranasal corticosteroid therapy were excluded from the study. The QOL was assessed using the 14-item mini rhinoconjunctivitis QOL questionnaire (MiniRQLQ). [25] It is a self-administered, valid, and reproducible questionnaire that is responsive to change. [26],[27] Individual items within the questionnaire are all equally weighted, and the results are expressed as a mean score per item. Overall, QOL score is estimated from the mean score of all items. [28] An average change in the score of 0.5 is considered clinically important because this is important in the patient's day-to-day life and is called the "minimal important difference" (MID). [29] The study was approved by the Institutional Ethical and Scientific Committee before commencement.

For every individual, eligible and consenting to participate in the study, a patient information sheet was filled. QOL of the subjects was measured using the MiniRQLQ. Subsequently, each individual underwent endoscopic inferior turbinectomy (with scissors and microdebrider) surgery for AR. After the surgery, intranasal fluticasone propionate nasal spray (two sprays per nostril per night, i.e., 100 mcg) was initiated and continued for 3 months. After 3 months, all patients were readministered the same MiniRQLQ to assess the change in QOL.

Data were collected using patient information sheet and were entered on Microsoft Excel spreadsheet. Simple measures of central tendency and dispersion were used to describe the data initially. Further, change in the absolute eosinophil count (AEC) and QOL was assessed using paired t-tests.

RESULTS

Baseline characteristics of the study population [Table 1]{Table 1}

A total of 50 subjects in an age group of 19-59 years were studied. Males constituted 72% while females constituted 28% of the study population. The mean age of the study population was 31.44 years (± 11.01). More than half of the study population belonged to the age group of 19-28 years (52%) followed by those in the age group of 29-38 years (22%). A majority of the study subjects were Hindus (82%) followed by Muslims (8%) and Christians (8%). A majority of the study subjects had completed their graduation (40%) followed by those who had completed their preuniversity course (20%), high school (12%), primary school (6%), and illiterates (4%). A majority of the study subjects were working as professionals (30%), followed by those that were self-employed (24%), students (22%), manual laborers (8%), and skilled laborers (6%).

A majority of the study subjects had Asthma (26%) followed by those that had hypertension (12%), diabetes mellitus (6%), and urticaria (4%). Most of those that had asthma were in the age group of 19-28 years (61%). A majority of the study population reported having a positive family history of allergy (36%). A little over one-fifth of the study population reported a history of tobacco (22%) and alcohol (22%) consumption each. A high proportion of the study population was having co-existing sinusitis (44%). More than half of those with co-existing sinusitis belonged to the age group of 19-28 years (53.6%). A majority of the study population were positive for "allergic skin prick tests" (94%). Most common allergen that gave a positive skin prick test was dust (54%) followed by mites (36%) and pollen (32%).

Absolute eosinophil count values

AEC was measured both before and 3 months after the "surgery with intranasal corticosteroid" therapy for all the study subjects. The mean AEC before the "surgery with intranasal corticosteroid therapy" was 517.66 (± 74.42). The mean AEC value reduced to 322.70 (± 54.68) 3 months after the "surgery with intranasal corticosteroid therapy." This difference was found to be statistically significant (0.001) ($t = 24.25$; $df = 49$).

Quality of life scores

QOL was measured both before and after the "surgery with intranasal corticosteroid" therapy for all the study subjects. The mean QOL scores before the "surgery with intranasal corticosteroid therapy" were 2.624 (± 0.445). The mean QOL scores reduced to 2.031 (± 0.386) 3 months after the "surgery with intranasal corticosteroid therapy." This difference was found to be statistically significant (0.001) ($t = 15.91$; $df = 49$).

Minimal important difference [Figure 1]{Figure 1}

An MID value of more than 0.5 is considered to be clinically significant. In this study, the MID between the mean QOL scores before and after "surgery with intranasal corticosteroid therapy" was calculated, and the average MID was found to be 0.59 (± 0.26). In addition, a majority (68%) of the study subjects showed this clinically significant difference of more than 0.5 between mean QOL scores before and after "surgery with intranasal corticosteroid therapy."

DISCUSSION

The mean age of the fifty subjects in the study population was 31.44 years (± 11.01), and this was similar to the mean age of the study populations in other studies [11],[17],[30] as well. Males constituted 72% of the study population while females constituted 28% of the study population. In population-based studies, [17],[30] usually there is an equal proportion of males and females in the study population. However, this study being a hospital-based study, the proportion is expected to be skewed because the sample is not randomly selected. The mean age of the population was 31.44 years and only 18% had diabetes mellitus and hypertension and all those who had diabetes were in the age group of 49-58 years.

Almost one-third of the study population had a history of asthma (26%) and urticaria (4%). In addition, a high proportion of

the study population (44%) was having co-existing sinusitis. It is a known fact that asthma, co-existing sinusitis, and urticaria are usually associated with AR. [10],[15],[19] Most of those who had asthma were in the younger age groups of 19-28 years. Other studies [10],[15] also showed a similar preponderance of asthma among the younger populations in their study groups. The family history of allergy is a significant factor associated with AR. In this study, we found 36% of the study subjects reported a positive family history of allergy. This is also corroborated by other similar studies. [10],[30] The most common allergen that gave a positive skin prick test was house dust (54%) followed by mites (36%) and pollen (32%).

The mean AEC value was 517.66 (± 74.42) before the therapy and this value reduced to 322.70 (± 54.68) 3 months after the therapy. AEC is an objective measure of allergy, and since allergic reaction was reduced by the therapy it is imperative that AEC also reduces accordingly.

Further, on comparing, the difference in the two means was statistically significant which in turn means that the therapy had a statistically significant impact on the AEC. QOL was the dependent outcome variable in this study. The mean QOL score before the therapy was found to be 2.624 (± 0.445) and it reduced to 2.031 (± 0.386) 3 months after the therapy. Further, on comparing, the difference in the two means was statistically significant.

The MID between the mean QOL scores before and after the therapy was calculated and the average MID was found to be 0.593 (± 0.26). An MID value of 0.5 and above is considered to be clinically significant. In other words, this improvement in QOL was clinically significant. Hence, we can safely infer from this that the QOL of patients with AR improved significantly, both clinically and statistically, after the surgery with intranasal corticosteroid therapy.

CONCLUSIONS

We conclude that within 3 months after the surgery and intranasal corticosteroid therapy, the mean AEC as well as the mean QOL scores reduced significantly indicating a reduction in the allergic reaction and an improvement in the QOL of patients suffering from AR, respectively. Based on the results of this study, for patients with moderate to severe AR, we recommend a combination therapy of inferior turbinectomy (done endoscopically with scissors and microdebrider) followed by a 3 months course of intranasal fluticasone propionate spray (100 mcg per nostril per day). This therapy has a significant positive impact on the QOL of patients suffering from moderate to severe AR.

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Conflicts of interest

There are no conflicts of interest.

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