

QUALITY OF LIFE ASSESSMENT IN CHILDREN AND THEIR CAREGIVERS SUFFERING FROM ALLERGIC RHINITIS AND/OR ASTHMA

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Abstract

Introduction: Asthma and Allergic Rhinitis (AR) are among the most prevalent diseases worldwide and they frequently persist throughout life. These have significant effect on physical, financial and mental wellbeing of patients and caregivers. There have been few attempts previously, assessing quality of life in affected families suffering from these diseases. However, data from developing countries are scarce. Quality of life (QOL) assessment in children and caregivers of patients suffering can help in symptomatic management and provide inputs for better utilization of resources to achieve optimal treatment. **Methods:** Patient and caregiver QOLs were ascertained using mPAQLQ and PACQLQ respectively in the study and correlated with disease severity and chronicity using parametric and non-parametric statistical tools. **Results:** There were 246 pairs of children diagnosed with Asthma and/or AR and their caregivers attending the Pediatric Allergy and Asthma clinic. Symptom score, emotional domain and activity limitation in children did not validate a statistically significant difference in QOL in various grades of AR/Asthma ($p=0.632$), ($p=0.772$), ($p=0.496$), ($p=0.918$) and ($p=0.384$), ($p=0.561$) respectively. Additionally there was no significant correlation between the severity of asthma and caregiver emotional disturbance ($p=0.594$) or caregiver activity limitation ($p=0.446$). **Conclusions:** Quality of life in children and caregivers where children are suffering from either AR or Asthma, or both has not shown any significant difference as per the disease severity or chronicity in various domains. There was no significant difference in quality of life noted as per change in age group, gender of patients or education status of caregivers.

Title Page

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Abstract

Introduction: Asthma and Allergic Rhinitis (AR) are among the most prevalent diseases worldwide and they frequently persist throughout life. These have significant effect on physical, financial and mental wellbeing of patients and caregivers. There have been few attempts previously, assessing quality of life in affected families suffering from these diseases. However, data from developing countries are scarce. Quality of life (QOL) assessment in children and caregivers of patients suffering can help in symptomatic management and provide inputs for better utilization of resources to achieve optimal treatment. Methods: Patient and caregiver QOLs were ascertained using mPAQLQ and PACQLQ respectively in the study and correlated with disease severity and chronicity using parametric and non-parametric statistical tools. Results: There were 246 pairs of children diagnosed with Asthma and/or AR and their caregivers attending the Pediatric Allergy and Asthma clinic. Symptom score, emotional domain and activity limitation in children did not validate a statistically significant difference in QOL in various grades of AR/Asthma ($p=0.632$)($p=0.772$), ($p=0.496$) ($p=0.918$) and ($p=0.384$), ($p=0.561$) respectively. Additionally there was no significant correlation between the severity of asthma and caregiver emotional disturbance ($p=0.594$) or caregiver activity limitation ($p=0.446$). Conclusions: Quality of life in children and caregivers where children are suffering from either AR or Asthma, or both has not shown any significant difference as per the disease severity or chronicity in various domains. There was no significant difference in quality of life noted as per change in age group, gender of patients or education status of caregivers.

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Introduction

An approximate 300 million people worldwide are suffering from asthma, with Indians constituting nearly 12% of the affected population, i.e. 37.9 million¹. An estimated 2% to 25% children and nearly 40% adults also suffer from allergic rhinitis(AR)². Association of asthma with AR is seen in 15% to 38% of patients, and asthma with nasal symptoms in 6% to 85% patients respectively. In addition, uncontrolled moderate-to-severe AR affects asthma control making AR a significant risk factor for asthma².

The first breakthrough study was the International Study of Asthma and Allergic Diseases in School Children (ISAAC) phase I carried out in 1995. Global prevalence, severity, and association with environmental risk factors of asthma, AR, and eczema were studied using a standardized validated tool and uniform methodology. Identifying the etiological factors formed the core basis of ISAAC phase II (1998) while the ISAAC phase III study (2001-2003) imitated phase 1 for evaluating 1.9 million children from 98 countries and found a wide heterogeneity in the prevalence of AR and eczema globally. In India, the ISAAC phase III showed the prevalence of AR and ARC as 11.3% (7.3%, 26.7%) and 3.9% (1.8%, 8.6%), respectively, in the 6-7-year-olds and 24.4% (4.1%, 45.7%) and 10.9% (0.9%, 23.6%) in the 13-14-year-olds, respectively³. The Global Asthma Network (The GAN) continued the work that ISAAC (concluded 2012) had initiated and extended the survey to include parents of children participating in the study to bridge the data gap about the prevalence of asthma, AR, and eczema in adults especially in the low- and middle-income countries¹.

Patients, suffering from allergic rhinitis, not only manifest troublesome nasal symptoms, such as, rhinorrhea, nasal congestion, sneezing, but also, often have to endure distressing non-nasal symptoms including headaches, fatigue, excessive thirst and sleep deprivation⁴. These allergies sometimes impede learning in children leading to reduced productivity and concentration⁵.

Quality of life (QOL) score is increasingly being used as the measure for determination of effectiveness of a particular treatment procedure for childhood asthma. Besides patients' physical health, this assessment encompasses the effects of disease on every aspect of patient's daily life, trying to assess their emotional, financial, and social well-being too⁶. There is no unanimity among the health fraternity whether the severity of disease alters the QOL of asthmatic children for the worse. Some studies do not consider any correlation between symptoms of poorly managed chronic asthma such as, wheezing, or frequent sleep disruption, including night awakenings etc., which adversely affect patients and their caregivers' daily life, and children's QOL indices, whereas other studies factor them in their results⁷.

The health-related quality of life (QOL) of rhinitis and asthmatic patients are deemed to be affected by demographic and socio-economic factors. In India, underdiagnosis, inadequate treatment, deceptive symptomatic names, such as 'cough', 'saans' and 'dama', a wide gap in healthcare facilities across different economic strata, and a lack of health insurance form important prevalent challenges. Cheaper oral formulations vanquish the widely available inhaled corticosteroids (ICS), β_2 -agonist and combination inhalers present in the market. Inadequate treatment still leads to yearly hospitalizations in more than 25% of patients as the myths of inhalers being habit-forming drugs are still widespread in our society.^(8,9)

Multiple studies during the pandemic reported infection, severity, and mortality of COVID-19 among patients with AR and/or asthma did not have any significant association with the ongoing long term medications. AR (all ages) and asthma (aged <65) were found to be protective factors against COVID-19 infection, but asthma did increase the risk for COVID-19 hospitalizations¹⁰. A Systematic Review and Meta-Analysis based on the 'Association between Allergic Rhinitis and COVID-19' analyzed the results of nine studies and found the prevalence of AR in patients with COVID-19 was 0.13 with an overall I^2 of 99.77% supporting that COVID-19 patients with AR are less prone to severe disease (odds ratio [OR] = 0.79, 95% CI, 0.52–1.18,) and hospitalization (OR = 0.23, 95%CI, 0.02–2.67,) than patients without AR¹¹.

Since there have been no studies available from this part of world to evaluate the QOL in children and their caregivers with varying severity of respiratory allergies, the objective of this study, planned by us, was to assess the QOL in children and their caregivers suffering from allergic rhinitis and/or asthma. The study hopes to highlight the QOL of both children and their caregivers and help provide inputs for better

utilization of resources to achieve optimal treatment.

Aims and Objective

To assess quality of life in children and caregivers of patients suffering from various grades of allergic rhinitis and/or asthma.

Sample size calculation:

Sample sizes were estimated individually for each item of quality of life (symptoms, emotions, activity limitation) for children and (emotions, activity limitations) for caregivers based on the study published by Nair, et al. Maximum sample size was found for the symptom item of quality of life of patients (4.512 ± 1.689)¹². The required sample size with an estimation of error of 5% and 95% confidence level was calculated to be 216. Thus the sample size of the study is 216 children and equal number of caregivers (216).

Following formula was used for calculating the sample size:

Sample Size (n) [?] $[Z_{1-\alpha/2} \sigma/d]^2$

Where $Z_{1-\alpha/2} = 1.96$ (For 95% confidence level)

σ is the standard deviation of the QOL score

d is the estimation error (5% of the expected average (4.512))

An inflation of 15% was added to compensate for non-response, so the total sample size was $216 + 30 = 246$

Material and Methods

The required approvals were obtained from the Institutional Review Board (IRB) committee and the Department of Paediatrics. A prospective observational study was conducted at Pediatric Allergy and Asthma clinic of Sir Ganga Ram Hospital, New Delhi, a 650-bedded tertiary care referral hospital of North India. Children with suspected allergic rhinitis and/or asthma, who presented to pediatric allergy or asthma clinic of a hospital-based set-up and satisfied inclusion criteria were made to fill a predesigned validated questionnaire to assess various domains of quality of life in children and their caregivers. Data collection was initiated after approval from hospital ethics committee and was started from January 2019 and continued till September 2019.

The inclusion criteria included children aged between 7- 18 years, suffering or have suffered from symptoms suggestive of allergic rhinitis and/or asthma who consented to being part of the study. Exclusion criteria included children with alternate respiratory comorbidities (aspiration pneumonia, respiratory complaints due to Myo-neuropathies, neonatal history of bronchopulmonary dysplasia, tracheal or bronchial lesions, vocal cord dysfunction), other chronic medical conditions like congenital heart disease, infectious etiology, patient in ICU or on home ventilation. Caregiver who spent 75% of time with the child was considered primary caregiver¹³.

Quality of life was defined as the measure of emotions, allergic rhinitis/asthma severity/symptoms, activity limitations and visits to emergency departments. **Asthma** is a heterogeneous disease, usually characterized by chronic airway inflammation. It is defined by the history of respiratory symptoms such as wheeze, shortness of breath, chest tightness and cough that vary over time and in intensity, together with variable expiratory airflow limitation. Based on GINA guidelines, Asthma is classified into intermittent, mild, moderate and severe variety⁸. [Annexure 1] **Allergic rhinitis** is an inflammation of the nasal membranes that is characterized by sneezing, nasal congestion, nasal itching and rhinorrhea in any combination². It is classified based on the ARIA guidelines. [Annexure 2]

Study tool

QOL was assessed in children and their caregivers using mPAQLQ and PACQLQ respectively¹³. [Annexure 3,4] mPAQLQ contains total 13 questions in three domains (6 for symptoms, 3 for activity limitations and 4

for emotions). Each questions was answered on a scale of 1- 7 (1 is worse and 7 is best). Similarly, caregivers' questionnaire contained total 13 questions in two domains (4 for activity limitations and 9 for emotions) which were also answered on 7 point scale. Mean of each domain was taken in patients and their caregivers and compared with disease severity and chronicity. Association of quality of life of children and caregiver with disease (AR/ Asthma) severity and chronicity using parametric and non-parametric statistical tools was seen. The questionnaires were used according to the mother tongue of the caregiver interviewed.

Data Analysis

Data were coded and recorded in MS Excel spreadsheet program. SPSS v23 (IBM Corp.) was used for data analysis. Descriptive statistics were elaborated in the form of means/standard deviations and medians/IQRs for continuous variables, and frequencies and percentages for categorical variables. Group comparisons for continuously distributed data were made using independent sample 't' test when comparing two groups. If data were found to be non-normally distributed, appropriate non-parametric tests in the form of Wilcoxon Test were used. Chi-squared test was used for group comparisons for categorical data. In case the expected frequency in the contingency tables was found to be <5 for >25% of the cells, Fisher's Exact test was used instead. Linear correlation between two continuous variables was explored using Pearson's correlation (if the data were normally distributed) and Spearman's correlation (for non-normally distributed data). Statistical significance was kept at $p < 0.05$.

Figure 1: Study Flow Chart

Observations and Results

A total of 246 pairs of children diagnosed with Asthma and/or AR and their caregivers attending the Pediatric Allergy and Asthma clinic during the study duration were included. The recruited children were in the age group ranging from 7-18 years of age with the mean \pm SD of age being (10.84 ± 3.78) years. Approximately 70% of subjects were in 7-12 years age group whereas only 30 % were adolescents. Among the studied patients, 149 (60.6%) were boys in contrast to 97 girls (39.4%).

Out of the 246 children, 20 (8%) were suffering from AR and 66 (27%) from Asthma alone respectively whereas two-third i.e. 120 (65%) had both AR and asthma. The study showed that 140 (56.9%) children had mild symptoms and 106 (43.1%) children had moderate to severe symptoms with male preponderance seen in both groups. Majority of the patients had persistent symptoms (191- 77.6%) with only 55 (22.4%) children being affected intermittently.

Only 129 (52.4%) caregivers fulfilled criteria to be primary caregivers. Majority of the caregivers were educated and approximately 96% had attained a graduate degree. There was no significant difference seen on comparison of the severity or chronicity of disease AR/Asthma and education status of the caregiver. ($p = 0.422$).

Emotional domain and activity limitation in children did not validate a statistically significant difference in QOL in various grades of AR/Asthma ($p=0.496$) ($p=0.918$) and ($p=0.384$), ($p=0.561$) respectively. There was no significant correlation between the severity of asthma and caregiver emotional disturbance ($p=0.594$). There was also no significant relationship between asthma severity and caregiver activity limitation ($p=0.446$) [Table I]

Discussion

Allergic rhinitis (AR) and asthma are among the most common diseases globally and they usually persist throughout life. There has been a visible spike in the rate at which people are contracting respiratory allergies across the world, of which allergic rhinitis and asthma are the most prominent; the former accounts for 20-30 % cases of respiratory allergies while the latter affect around 15 % of the population^{2,14}. These allergies, with increase in severity, have a debilitating effect on the productive, social, and emotional aspects of patients, disrupting their and their caregiver's daily lives¹⁵. Despite such significant effects, respiratory allergies are generally underestimated.

Furthermore, there is no unanimity among studies of childhood asthma and allergic rhinitis highlighting the connection between the severity of the disease and child's quality of life. Some studies report that severe or poorly managed asthma cause impairment of social, physical, and academic lives of paediatric patients, whereas several other studies disregard it^(7,16). The paucity of studies conducted in India especially in paediatric patients for measurement of QOL of patients and caregivers made us conduct this study using mPAQLQ and PACQLQ questionnaires in our population, where children were suffering from asthma and/or rhinitis.

Approximately 70% of subjects of our study were in the 7-12 years age group whereas only 30 % were adolescents. Similar distribution was seen in previous study also. 66% out of 69 patients were in the age group of 7-12 years and 33 % in 13- 17 years age group¹². This could be either because respiratory allergies affect more in lower age group or adolescent age group patients get distributed among Pediatric and adult physicians.

Boys (60.6%) outnumbered girls (39.4%) in the study cohort. The trend was similar to other diseases over past few years. The study done by Scala et al in 56 Brazilian children showed female predominance in the study population¹⁷. A study done in Indian Population by Singh and associates in 20 children showing quality of life score in Indian asthmatic children receiving inhaled corticosteroid therapy also showed higher male proportion (male=55%)¹⁸. The male preponderance may be explained by preferential sex selection either by disease or by society for seeking medical help in developing countries.

Out of 246 children, 8% were suffering from AR and 27% from Asthma alone whereas two-third (65%) had both symptoms. A multicenter study done in India, by Jaggi V et al among 1161 adult asthmatic patient showed the prevalence of co-existing AR in asthma patients to be 65.24%¹⁹. In western population, prevalence of AR with Asthma was about 50-100% as reported by Gaugris et al²⁰. Our study findings of combined involvement of nose and airways highlights the concept of 'united airway disease'.

Out of 69 asthmatic patients, Nair et al in their study had 74% patients of moderate severe asthma whereas mild variety were only 26 %¹². Boran P et al conducted study in 305 Turkish children suffering from asthma. Among them, 82% of children had intermittent asthma and 18% had persistent asthma. Sixty-four percent of asthmatics also had allergic rhinitis²¹. In our study, mild (56%) and persistent (78%) grade of asthma were more than the moderate- severe or intermittent type. This could be possibly because moderate severe cases used to get admitted earlier and report less in OPD. More people presented with persistent disease rather than being affected intermittently for 3-4 days many times in a year. This can be explained by possible poor compliance with medications or incorrect inhaler techniques.

When compared with the education of the caregiver, the severity or chronicity of disease (AR/Asthma), there was no significant difference seen ($p = 0.422$) as per the education of caregiver. This could possibly be because the study was done in urban population, 90% of whom had attained a bachelor's degree so had better understanding of disease process and accessibility to healthcare was easy for them. Additionally, a rare possibility could be their ignorance and hence difficulty to perceive the difference in QOL of themselves as well as their children. A study conducted by Walker J et al involving subjects from 201 rural families reached to a conclusion that perception about the quality of life in subjects depends upon how well the asthma in children was controlled rather than their education level. For instance, it was observed during the course of study that in cases where asthma severity in children aggravated, not only such children missed school their parents had had to take their days off from work to look after their wards, resulting in a diminished sense of quality of life²². Juniper et al reported that there are significant changes in QOL as the severity of Asthma increases ($p < 0.001$). On the other hand, Annett et al and Montalto et al found no difference in QOL based on the severity of asthma^{13,15,23,24}. A systematic review with meta-analysis on asthma control in the quality of life levels of asthmatic patients' caregivers highlighted that asthma control levels can influence the total HRQOL scores of parents or relatives of children and adolescents with asthma²⁵.

The result in emotional domain in children showed no significant difference in QOL in various grades of AR/Asthma ($p=0.496$) ($p=0.918$) and agreed with past studies. A study done among 305 Turkish children

by Boran P and colleagues showed that severity of asthma and presence of allergic rhinitis were found to be significant factors associated with impaired QOL of these children in other domains except for emotional function²¹. Diette et al observed among 438 children and their caregivers that nighttime awakening reduced attendance of both child and their caregivers in school and at workplace, respectively²⁶.

It was found that activity limitation domain of children showed significant difference with the severity of asthma in many studies. Study done by Leynart in 850 French population of young adults in two centers using SF-36 questionnaire suggested that AR alone causes less impairment of physical activity than with patients of both allergic rhinitis and asthma⁵. Our study results were inconsistent with the others as it was seen that there is no significant difference between activity limitation with the different grades or severity of AR/Asthma ($p=0.384$), ($p=0.561$). This could be possibly because of limited sample size and because a great chunk of our sample size belonged to mild variety whose activities were less limited.

A study conducted by Callery et al in 25 British children aged from 9 to 16 years of age group along with their caregivers also reported change in QOL of parents with the severity of asthma in children²⁷. Similarly, Juniper et al reported significant change in QOL of caregiver in both the domains (emotional and activity limitation) ($p<0.0001$) with disease severity¹³. A Saudi Arabian study by Nafeesa et al concluded that caregiver emotional status is vital for the success of asthma management among patients. In addition, effective control status is also required to ensure low levels of anxiety among patients and their caregivers²⁸. In our study, when compared with caregiver emotional and activity limitation score for calculating QOL score there was no statistically significant difference (p value = 0.549 and 0.446 respectively).

The possible reason for no significant changes seen in PACQLQ score was that parent's perception of QOL related to disease severity was less. Secondly, our study was single visit study. No follow up questions post treatment of AR/Asthma were asked. So, any change noted in QOL of parents could not be assessed. Thirdly, for cases below 12 years of age, it is not prudent to form an opinion about the impact of asthma severity on child's quality of life based on parent's reportage alone. According to research done by Callery et al, parents report was insufficient to get an understanding of the children's quality of life as they failed to provide complete information about the disease severity²⁹. Lastly, our small sample size could be another added reason.

Limitations

This study presented the impact of AR and/or Asthma severity on the QOL from the viewpoint of both parent and child. Yet, there were some study limitations including a small sample size, single center time bound study with single interaction and restricted sample size. Also, parents and children in this study may have suffered from some recall bias because questions were asked regarding symptoms over a month time. A greater portion included smaller age group children so perception of QOL in those children was based on their parents' judgement.

Conclusion

Quality of life in children and caregivers where children are suffering from either AR or Asthma, or both has not shown any significant difference as per the disease severity or chronicity in various domains. There was no significant difference in quality of life noted as per change in age group, gender of patients or education status of caregivers. Further, multicentric, prospective, observational studies with larger sample sizes are required to highlight the effect on QOL especially in a country like ours where there is a great burden of the disease. Awareness is also required about the disease process and its consequences on the quality of life.

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