

# Assessment of Quality of Life in Asthmatic Patients on Inhaled Corticosteroids: An Observational Study

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## ABSTRACT

**Introduction:** Corticosteroids play a pivotal role in the treatment of the asthma. They rapidly reduce the number of eosinophils in the blood and tissues and inhibit their degranulation, suggesting that sputum eosinophilia could be a good predictor of response to inhaled corticosteroids. Chronic diseases like asthma have significant effects on patients' health-related quality of life (HRQoL). HRQoL measures additional indices as compared to objective measurements like spirometry. Objective: To assess and compare disease-specific quality of life in asthma patients using St. George's Respiratory Questionnaire (SGRQ) receiving inhaled corticosteroids.

**Material and Methods:** Patients were enquired for their duration of illness, other co morbidities (if present), history of smoking and familial history of the illness. Pattern of asthma was duly assessed. For Health-related Quality of life assessment, Saint George's Respiratory Questionnaire (SGRQ) was used in the study after obtaining due permission from the concerned authority at St George's, University of London.

**Results:** Mean age of the study population was found to be  $36.17 \pm 18.77$  years. Mean duration of illness for the asthmatics was  $10.19 \pm 11.08$  years. Majority i.e. 69% denied of having any familial history of asthma, while 31% confirmed having the same. Smoking status was enquired among the study subjects, which revealed that 85% were non-smokers, while 9% were past smokers and 6% were current smokers. Pattern of asthma was found to be seasonal for 65% patients while perennial for 35% patients. Baseline symptoms score was  $61.45 \pm 15.78$ , which was reduced to  $48.19 \pm 18.73$  after 3 months on inhaled corticosteroids therapy. Baseline activity score was  $49.67 \pm 15.34$ , which was reduced to  $41.51 \pm 18.52$  after 3 months on inhaled corticosteroids therapy. Baseline impact score was  $48.79 \pm 16.85$ , which was reduced to  $38.69 \pm 18.14$  after 3 months on inhaled corticosteroids therapy.

**Conclusion:** There was evidence for an early QoL improvement on inhaled corticosteroids in moderate and severe persistent asthma.

**Keywords:** Asthma, HRQoL Measures, St. George's Respiratory Questionnaire (SGRQ)

may occur several times in a day or week in affected individuals, and for some people become worse during physical activity or at night. During an asthma attack, the lining of the bronchial tubes swell, causing the airways to narrow and reducing the flow of air into and out of the lungs. Risk factors for developing asthma include inhaling asthma "triggers", such as allergens, tobacco smoke and chemical irritants. Asthma has a relatively low fatality rate compared to other chronic diseases.<sup>2</sup> The number of disability-adjusted life years (DALYs) lost due to asthma worldwide has been estimated to be currently about 15 million per year. Worldwide, asthma accounts for around 1% of all DALYs lost, which reflects the high prevalence and severity of asthma. The number of DALYs lost due to asthma is similar to that for diabetes, cirrhosis of the liver, or schizophrenia. The economic cost of asthma is considerable both in terms of direct medical costs (such as hospital admissions and cost of pharmaceuticals) and indirect medical costs (such as time lost from work and premature death).<sup>1</sup>

The causes of asthma are yet to be completely understood. However, an improved understanding of the pathophysiology of asthma has led to the creation of guidelines for the long term management of this disease. Controller medications,

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## INTRODUCTION

It is now estimated that as many as 300 million people of all ages, and all ethnic backgrounds, suffer from asthma and the burden of this disease to governments, health care systems, families, and patients is increasing worldwide.<sup>1</sup> Asthma is a major chronic non-communicable disease characterized by recurrent attacks of breathlessness and wheezing, which vary in severity and frequency from person to person. Symptoms

particularly inhaled corticosteroids, should be administered daily to reduce and control airway inflammation. Over the past 50 years, there have been numerous randomized clinical trials that have established corticosteroids as the cornerstone of anti-inflammatory therapy in adults presenting to the emergency department or hospitalized for acute asthma. Corticosteroids reduce the amplification of the inflammatory cascade by altering transcriptional and post-transcriptional regulation, and may also have non-genomic actions.<sup>3</sup> If symptoms persist despite inhaled corticosteroid therapy, then long-acting inhaled  $\beta$  adrenoceptor agonists may provide additional benefit by improving control of asthma symptoms.

Recurrent asthma symptoms frequently cause sleeplessness, daytime fatigue, reduced activity levels and school and work absenteeism imposing restrictions on the physical, emotional, and social life of a patient, leading to impaired coping capacity and an impact on their careers and quality of life (QOL). QOL includes a large set of physical and psychological characteristics assessing the problem in the social context of life style.<sup>4</sup> Health-related QOL (HRQOL) is defined as “the functional effects of an illness and its therapy, as perceived by the patient”.<sup>5</sup> Clinical intervention in any chronic illness should result in improvement of QOL. The assessment of HRQOL evaluates its beneficial effect on health status as well as its cost effectiveness as it is an important component of health care, and, increasingly, an outcome measure in the treatment of chronic illnesses. Several studies have examined QOL in asthma. Patients with severe asthma tend to have lower general QOL scores than to patients with milder disease.<sup>6</sup> In recent years, various generic and specific instruments have been developed to estimate, in a multidimensional way, the impact that various diseases have on health-related quality of life. The Saint George’s Respiratory Questionnaire (SGRQ), developed by Jones et al<sup>7</sup> is a specific questionnaire for assessing quality of life in patients with chronic respiratory diseases. It has been translated, cross-culturally adapted, and validated for use in several countries across the globe.

There is dearth of data in Indian context adjudging the quality of life among asthmatic patients on inhaled corticosteroids. Therefore, the study was planned to assess the health related quality of life using SGRQ among a selected asthmatic population who were on inhaled corticosteroid therapy.

## MATERIAL AND METHODS

An observational study was conducted in patients attending the outpatient clinic of Chest and TB Department, Index Hospital, Indore. Permission of the Institutional Ethical Committee was obtained for conducting the study. Written informed consent was taken from all the subjects prior to their inclusion into the study. Demographic and clinical data were collected in a specially predesigned and pre-validated customized data collection sheet. Patients were enquired for their duration of illness, other co morbidities (if present), history of smoking and familial history of the illness. Pattern of asthma was duly assessed. For Health-related Quality of

life assessment, Saint George’s Respiratory Questionnaire (SGRQ) was used in the study after obtaining due permission from the concerned authority at St George’s, University of London. There are three components of the SGRQ calculator, namely:

**Symptoms score** - This component is concerned with the effect of respiratory symptoms, their frequency and severity.

**Activity score** - This component is concerned with activities that cause or are limited by breathlessness

**Impacts score** - This component covers a range of aspects concerned with social functioning and psychological disturbances resulting from airways disease

A Total score also summarizes the impact of the disease on overall health status.

Quality of life was thus duly assessed with the help of these components at baseline and during follow-up visits at 15, 30 and 90 days.

### Inclusion criteria

1. A random sample of 100 asthmatic patients aged above 18 years on inhaled corticosteroids for more than three months.
2. Those who understood the purpose of the study and were consented to be a part of the study by signing an Informed consent form.

### Exclusion criteria

1. Subjects on oral steroids in the past 6 months,
2. Subjects suffering from any significant co-morbidities, acute infective exacerbations in the past 4 weeks and
3. Those who were pregnant or lactating.
4. Those unable to comprehend for other reasons

## RESULTS

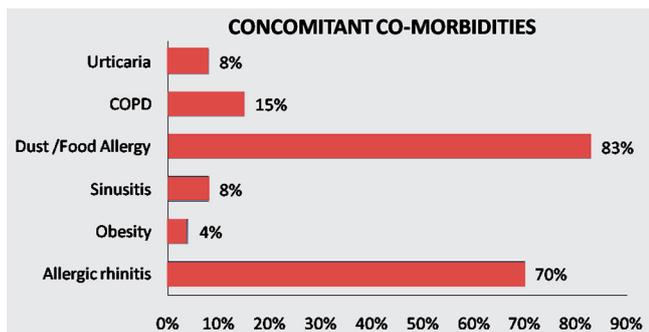
A total of 100 asthmatic patients were assessed in our study. In our study we found that male represented the majority population with 51%, while female represented 49% of the study population. Mean age of the study population was found to be  $36.17 \pm 18.77$  years.

Mean duration of illness for the asthmatics was  $10.19 \pm 11.08$  years. Majority i.e. 69% denied of having any familial

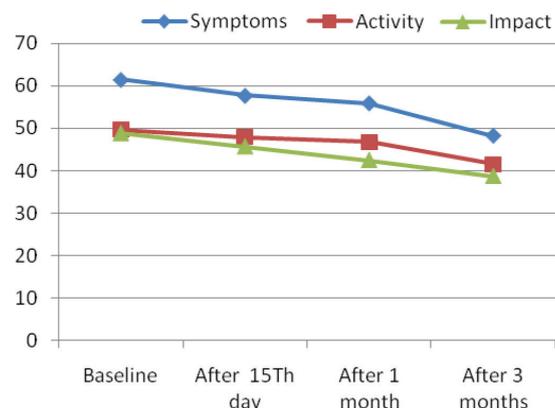
<b>Gender n (%)</b>	
Male	51 (51%)
Female	49 (49%)
Mean (SD) age, years	$36.17 \pm 18.77$ years
Duration of disease	$10.19 \pm 11.08$ years
<b>Family History n (%)</b>	
Positive	31%
Negative	69%
<b>Smoking History n (%)</b>	
Past smokers	9%
Smokers	6%
Non smokers	85%
<b>Pattern of Asthma</b>	
Seasonal	65%
Perennial	35%
<b>Table-1: Demographic and Clinical Characteristics of Asthma Patients (N=100)</b>	

Quality of life SGRQ domains (mean ± SD)	Baseline	After 15 <sup>th</sup> day	After 1 month	After 3 months	CI (95%)
Symptoms	61.45± 15.78	57.67± 16.75	55.89 ± 20.57	48.19±18.73	P <0.0001 CI 8.4303 - 18.0897
Activity	49.67± 15.34	47.96± 18.35	46.74± 18.57	41.51±18.52	P=0.0008 CI 3.4177-12.9023
Impact	48.79± 16.85	45.68± 17.89	42.48± 16.69	38.69±18.14	P <0.0001 CI 5.2176-14.9824
Total score	51.48± 18.95	49.18± 18.49	46.76± 18.27	41.15±16.45	P <0.0001 CI 5.3814 - 15.2786

**Table-2:** Demographic and Clinical Characteristics of Asthma Patients (n=100)



**Figure-1:** Co-morbidities among asthma patients (N=100)



**Figure-2:** Quality of life as per SGRQ domains

history of asthma, while 31% confirmed having the same. Smoking status was enquired among the study subjects, which revealed that 85% were non-smokers, while 9% were past smokers and 6% were current smokers. Pattern of asthma was found to be seasonal for 65% patients while perennial for 35% patients (Table 1).

Concomitant co morbidities with conditions like allergic rhinitis, obesity, sinusitis, dust/food allergy, COPD, urticaria was judged. 83% reported of having dust/food allergy as a co-morbid condition, while 70% reported of having allergic rhinitis [Fig. 1].

Quality of life was adjudged based on SGRQ questionnaire. All three components of SGRQ calculator (symptoms, activity and impact) were found significantly decreased after 3 months when compared to the baseline score [Table 2/ Fig. 2]. The total score which summarized the impact of the disease on overall health status was thus found decreased at the end of the study period. Scores were expressed as a

percentage of overall impairment where 100 represents worst possible health status and 0 indicates best possible health status. Baseline symptoms score was 61.45± 15.78, which was reduced to 48.19±18.73 after 3 months on inhaled corticosteroids therapy. Baseline activity score was 49.67± 15.34, which was reduced to 41.51±18.52 after 3 months on inhaled corticosteroids therapy. Baseline impact score was 48.79± 16.85, which was reduced to 38.69±18.14 after 3 months on inhaled corticosteroids therapy [Table 2/ Fig. 2].

**DISCUSSION**

Asthma, a major public health problem, is a chronic, reversible, inflammatory disease of the airways, whose incidence is increasing worldwide. The high burden of asthma, which accounts for about 1 in every 250 deaths worldwide, appears to be related to poor asthma control, which is associated with more frequent asthma symptoms, worse pulmonary function, increased health service use, and increased functional impairment.<sup>8,9</sup> The availability of effective treatments suggests that asthma can be well controlled in most patients, yet the vast majority of asthmatics remain poorly controlled. Achieving optimal asthma control relies upon several behavioral factors, including minimizing exposure to known triggers (eg, pets, dust) and engaging in appropriate health behaviors (eg, avoiding tobacco smoking and adhering to medication).<sup>8,10</sup>

Our study showed male predominance as compared to females in the asthmatic population. Mean age of the study population was found to be around 36 years while average duration of illness for the asthmatics was over 10 years. Genetics also play an important causative role, as indicated by familial aggregation and the identification of candidate genes and chromosomal regions linked to asthma risk. Thus familial history is a significant risk predictor of asthma. In our study population, majority i.e. 69% denied of having any familial history of asthma, while 31% confirmed having the same. The studies varied in definitions of positive family history and asthma phenotype and used study populations with asthma prevalence ranging from 2% to 26%. Nevertheless, family history of asthma in one or more first-degree relatives was consistently identified as a risk factor for asthma. In ten studies, sensitivity and predictive value of a positive family history of asthma could be calculated: sensitivity ranged from 4% to 43%, positive predictive value from 11% to 37%, and negative predictive

value from 86% to 97%. Although a positive family history predicts an increased risk of asthma, it identifies a minority of children at risk. Positive family history may have utility in targeting some individual prevention efforts, but the low positive predictive value limits its value as a means to direct environmental remediation efforts.<sup>11,12,13</sup> Being a major contributor to the cause of this illness, smoking status needs to be adjudged among the study population. Our study revealed majority being presently non-smokers, while few being current or past smokers. Abstinence from smoking must be duly encouraged.<sup>14</sup>

Planning effective and efficient strategies for managing asthma requires proper identification of the clinical pattern of disease in the patient to be treated. Our present study shows increased prevalence of seasonal asthma as compared to perennial asthma in study population. Various concomitant co morbidities are considered highly relevant for asthma control and exacerbation outcomes. In our set up, subjects were found to be presenting with co-morbid conditions like allergic rhinitis, obesity, sinusitis, dust/food allergy, COPD and urticaria. 83% reported of having dust/food allergy as a co-morbid condition, while 70% reported of having allergic rhinitis. Allergic rhinitis and asthma commonly coexist. Allergic rhinitis is a risk factor for asthma and may even be on the same disease continuum as asthma. The presence of concomitant AR in adult asthma was associated with worse asthma outcomes resulting in a higher risk of asthma-related emergency hospital care in some studies. The evaluation and consequent management of AR may improve asthma outcomes according to national and supranational guidelines.

People with asthma report impacts on the physical, psychological and social domains of quality of life. Health-related quality of life (HRQoL) measures have been developed to complement traditional health measures such as prevalence, mortality and hospitalization as indicators of the impact of disease. The inclusion of health and patient-focused measures of impact in population monitoring for asthma is important for guiding clinical management, predicting health outcomes, formulating clinical policy and assisting in the allocation of resources. A range of HRQoL measurement instruments is available and choosing the most appropriate requires consideration of the context in which it will be implemented and the purposes of the data collection.<sup>15,16</sup> Asthma is a chronic, reversible inflammatory disorder of the airways of the lungs. It reduces adolescents' physical health (e.g., obesity, physical limitations), psychological health (eg, anxiety, depression, self-esteem), and social health (e.g., social interaction, peer acceptance). It also adversely affects their health-related quality of life (HRQoL), defined as an individual's or group's perceived physical or mental health over time.<sup>16,17-20</sup>

National asthma guidelines ask physicians to assess comprehensively patients' health including evaluations of patients' perceptions of the impact of asthma and asthma management on their QOL (eg, physical functioning and emotional well-being). Improving patient well-being is

recommended as a primary goal of treatment. Therefore, it is important to include QOL as a dimension of outcome measurement.<sup>20</sup>

Health-related quality of life (HRQL) has thus become an important outcome in respiratory patients as proved by the development of several respiratory disease-specific HRQL questionnaires in recent years. Among them, the St. George's Respiratory Questionnaire (SGRQ) has become one of the most widely used instruments for assessing HRQL in respiratory patients, and has been translated into several languages. The SGRQ is designed to measure the impact of chest disease on health related quality of life and well being. It can be used in COPD as well as in asthma. The responses to its 50 items can be aggregated into an overall score and three sub-scores for symptoms, activity, and impact. The number of response options per question varies from two to five. Responses are weighted and scores are calculated by dividing the summed weights by the maximum possible weight and expressing the result as a percentage, 0% being the best possible score and 100% the worst.<sup>21,22</sup> The weights appear to be similar in different countries and languages. The minimally clinically important response to treatment is defined as an improvement of 4% on the separate domains and the total score. Our study reported improvement in HRQoL after a period of three months as compared to baseline data in asthmatic patients placed on ICS therapy.

Study by Sabin T showed significant decrease ( $P < 0.05$ ) in each SGRQ domains and total scores as well as improvement in FEV(1) ( $P < 0.05$ ) was observed in all study subjects. A significant early response ( $P < 0.05$ ) was noted after 15 days treatment in patients receiving FP with respect to SGRQ (activity, impact and total) scores and dyspnea indices, but not FEV(1). This improvement with FP was due to its greater effect in patients with moderate and severe persistent asthma. No difference was noted subsequently in all outcome measures studied until 6 months.<sup>23</sup>

A study limitation is related to its conduction among a sample of asthmatic who had particular characteristics excluding those with other chronic conditions other than asthma. All of our patients were outpatients undergoing regular check-ups in general and specialized tertiary hospitals. Therefore, our patients were not representative of all asthmatics, which restrict the possibility of extrapolating our findings to the asthmatic population in general.

## CONCLUSION

This observational study confirms that HRQL (Health-related Quality of life assessment, Saint George's Respiratory Questionnaire (SGRQ)) is considerably impaired in asthma patients and worsens with disease deterioration and higher comorbidity. Findings underline the need of diagnosing and treating comorbid conditions in asthma patients on inhaled corticosteroids health status could be improved.

## Ethical approval

The study protocol was approved by the Institutional Ethics Committee

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