

## Original Research Article

# Correntional study of the health-related quality of life, chronic obstructive airway disease in Northern India, New Delhi

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## ABSTRACT

**Background:** The Global Initiative for Chronic Obstructive Lung Disease (GOLD) defines chronic obstructive pulmonary disease (COPD) as “a disease state characterized by airflow limitation that is not fully reversible. Due to progressive airflow limitation, the patients become increasingly symptomatic leading to worsening in their health-related quality of life (HRQOL). Objective of present study was to examine that correlation of health related quality of life with the chronic obstructive pulmonary disease.

**Methods:** One hundred twenty consecutive stable COPD patients (diagnosed as per GOLD guidelines), without any co-morbid conditions (diabetes, congestive heart failure, coronary artery disease, hypertension) were recruited in this study after intuitional ethical clearance and informed consents. The health-related quality of life (HRQOL) was assessed using Hindi SGRQ-C. Forced expiratory volume in first one second (FEV1), forced vital capacity (FVC) and FEV1/FVC% and reversibility were measured using Spirolab III (Medical International Research USA, Inc.). The descriptive and the Pearson's correlation coefficient were done in data treatment with SPSS version 20.

**Results:** The component of SGRQ scores were as follows: Symptom score:  $31.27 \pm 14.6$  (range 2.3-64); Activity score:  $59.01 \pm 23.08$  (range 0-100); Impact score  $42.19 \pm 22.25$  (range 0-88.8) and the total score was  $= 45.34 \pm 17.96$  (range 1.1-88.6). There were significant negative correlations between all the parameters of SGRQ and FEV1% predicted (i.e. with lower FEV1% parameters of SGRQ will be high).

**Conclusions:** Indian patients with COPD show significantly reduced HRQOL as measured by disease specific questionnaire SGRQ, similar to COPD patients in other countries. In our study, only FEV1 % predicted was significantly correlated with HRQOL, all other measures including GOLD staging were not significantly associated with HRQOL.

**Keywords:** Air way disease, Chronic pulmonary, Quality of life

## INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is the most common chronic lung disease in the world and is a major cause of morbidity and mortality worldwide.<sup>1</sup> The Global Initiative for Chronic Obstructive Lung Disease (GOLD) defines chronic obstructive pulmonary disease

(COPD) as a disease state characterized by airflow limitation that is not fully reversible. Diagnosis of COPD should be considered in any patient who has symptoms of cough, sputum production, or dyspnea, and/or a history of exposure to risk factors for the disease. The presence of a post bronchodilator forced expiratory volume in one second (FEV1) <80% of the predicted value in

combination with an FEV1/FVC <70% confirms the presence of airflow limitation that is not fully reversible.<sup>2</sup>

The prevalence of COPD in India according to the Indian study on epidemiology of asthma, respiratory symptoms and chronic bronchitis in adults I and II (INSEARCH I and II) study was 3.67% (4.46 and 2.86% among males and females, respectively).<sup>3</sup> With the increasing prevalence of smoking in developing countries, it is projected that COPD-related mortality and morbidity will dramatically impact Asian and African countries.<sup>4</sup> As the condition progresses, patients with COPD experience a progressive deterioration and disability, which lead to a worsening in their health-related quality of life (HRQOL).

However, it has been confirmed that the evaluation alone of the severity of COPD, measured by the degree of reduction of the FEV1, does not provide sufficient information to establish the health condition perceived by the patients. The interest for HRQOL measurement in patients with COPD has grown in recent years. HRQOL encompasses the physical, functional, emotional, and social well-being of the patient.<sup>5</sup> The HRQOL can be quantified through various health evaluation questionnaires, both general and specific, widely validated.<sup>6</sup> The former covers a broad range of dimensions, enable the comparison between groups of patients with different diseases, and facilitate the detection of problems or unexpected effects.<sup>7</sup>

It is generally agreed that improving the health of subjects is an important goal of a therapeutic intervention in COPD.<sup>8</sup> It is also widely accepted that medical interventions should aim to improve not only objective clinical outcomes, but also patient-reported outcomes such as HRQOL.<sup>9</sup>

Objective of present study was to examine that correlation of health-related quality of life with the chronic obstructive pulmonary disease.

## METHODS

One hundred twenty consecutive stable COPD patients (diagnosed as per GOLD guidelines), without any comorbid conditions (diabetes, congestive heart failure, coronary artery disease, hypertension) were recruited in this study after intuitional ethical clearance and informed consents.

### Inclusion criteria

This study will include confirmed cases of COPD who have been

- without any episode of acute exacerbation for past 2 months,
- >40 years of age,
- Current and past smokers and nonsmokers.

### Exclusion criteria

- Patient who are in acute exacerbation during investigation,
- Patients of asthma,
- Patients with any other comorbid condition (Diabetes, Congestive heart failure, Coronary artery disease, Hypertension)
- Patients having other respiratory diseases like bronchiectasis, tuberculosis.

### Sampling process

One hundred twenty patients of confirmed cases of stable COPD (Diagnosed as per GOLD guidelines), aged >40 years and undergoing treatment at the Chest Clinic and Medicine Outpatient Department of the Lok Nayak Hospital, were included in the study. Patients with any other comorbid condition (Diabetes, Congestive heart failure, Coronary artery disease, Hypertension), with any other respiratory disease (Asthma, Bronchiectasis, Past tuberculosis) and patients with acute exacerbation during study or with any episode of acute exacerbation for past two months were excluded from the study. Informed consent was taken from all the participants. These patients were completed history taking and physical examination on department of medicine. Particulars of the patients such as name, age, sex, and pack years of smoking were noted in a pre-structured Performa. Routine hematological and biochemical investigations, X-ray chest PA view and an ECG were carried out for all patients.

Spirometry was performed using Spirolab III (Medical International Research USA, Inc.). Pre- and post-bronchodilator (salbutamol 400 mcg) maneuvers were done by qualified respiratory therapists following American Thoracic Society standards<sup>6</sup>. COPD was documented by airflow obstruction showing forced expiratory volume in 1 second (FEV1)/forced vital capacity (FVC), 70% and less than 200 cc increases in FEV1 post bronchodilator. Disease severity was classified according to GOLD criteria.

The HRQOL was assessed using SGRQ-C. The SGRQ has been used extensively for assessing QOL in patients with COPD and several other chronic lung diseases.<sup>10-12</sup> It is sensitive, valid, reliable and responsive among patients with COPD. It contains 50 items with 76 weighted responses that cover three domains: symptoms – distress due to respiratory symptoms, activity – disturbances of physical activity and impact– overall impact on daily life and well-being. In addition to the domain scores, there is also a total score. This questionnaire which was forward and back translated in Hindi language was administered to each participant. The instrument is designed to elicit a patient's own opinion about his/her health. Patients were requested to complete the questionnaire themselves without assistance, as correctly and as completely as they could, and missing data was recorded as such. Scores are

expressed as a percentage of overall impairment where 100 represent the worst possible health status and 0 indicates the best possible health status. An Excel-based scoring calculator system was used in all patients, to calculate the symptoms, activity, impact, and total score.

### Statistical analysis

The Pearson's correlation coefficient (r) was used to assess the relationships between SGRQ scores, FEV1% predicted and other variables. A P-value of <0.05 was considered to be statistically significant.

## RESULTS

Finding of the present study shows that the Disease of severity (as measured by GOLD guidelines), HRQOL and Lung function parameters is shown in Table 1. Maximum number of the patients were in stage 4 (40.8%) and 3(36.7%), while stage 1 had only 1 (0.8%) cases.

Reveal that the Table 1 suggested that the HRQOL of the patients was determined by SGRQ score. The Mean SGRQ score for symptom, activity, impact and total was  $31.27 \pm 14.61$ ,  $59.02 \pm 23.08$ ,  $42.19 \pm 22.25$  and  $45.34 \pm 17.96$ . Mean values of FEV1 L, FEV1 % predicted, FEV1/FVC %, FVC L, PEF L/min were  $1.03 \pm 0.45$ ,  $37.23 \pm 15.95$ ,  $49.46 \pm 10.39$ ,  $2.03 \pm 0.65$ ,

$2.9 \pm 1.31$  respectively. We have correlated HRQOL as determined by SGRQ score and various health parameters (Table 2). Lung function as measured by FEV1 % predicted showed significant negative correlation with all the parameters of SGRQ score; indicating that poorer HRQOL was associated with poorer lung function.

**Table 1: GOLD staging, HRQOL and spirometry of the COPD patients (N=120).**

| Category   |                  | Mean $\pm$ SD (range) or N (%) |
|------------|------------------|--------------------------------|
| GOLD Stage | 1                | 1 (0.8%)                       |
|            | 2                | 26 (21.7%)                     |
|            | 3                | 44 (36.7%)                     |
|            | 4                | 49 (40.8%)                     |
| SGRQ score | Symptom score    | $31.27 \pm 14.61$ (2.3-64)     |
|            | Activity score   | $59.02 \pm 23.08$ (0-100)      |
|            | Impact score     | $42.19 \pm 22.25$ (0-88.6)     |
|            | Total score      | $45.3455 \pm 17.96$ (1.1-88.6) |
| Spirometry | FEV1 L           | $1.03 \pm 0.45$ (0.32-2.25)    |
|            | FEV1 % predicted | $37.23 \pm 15.95$ (12-88)      |
|            | FEV1/FVC %       | $49.46 \pm 10.39$ (28.72-69)   |
|            | FVC L            | $2.03 \pm 0.65$ (0.79-3.87)    |
|            | PEF L/min        | $2.9 \pm 1.31$ (0.81-6.82)     |

**Table 2: the correlation between HRQOL with FEV 1% predicted and other parameters.**

| Category              |   | SGRQ symptoms | SGRQ activity | SGRQ impact | SGRQ total |
|-----------------------|---|---------------|---------------|-------------|------------|
| FEV1 % predicted      | r | -0.217        | 0.256         | 0.192       | 0.246      |
|                       | p | 0.017         | 0.005         | 0.036       | 0.007      |
| FEV1/FVC %            | r | -0.092        | -0.160        | -0.065      | -0.108     |
|                       | p | 0.318         | 0.081         | 0.479       | 0.239      |
| FVC L                 | r | -0.143        | -0.276        | -0.187      | -0.245     |
|                       | p | 0.119         | 0.002         | 0.041       | 0.007      |
| PEF L/min             | r | -0.164        | -0.298        | -0.156      | -0.232     |
|                       | p | 0.074         | <0.001        | 0.090       | 0.011      |
| Age                   | r | -0.149        | 0.155         | -0.059      | 0.014      |
|                       | p | 0.105         | 0.091         | 0.524       | 0.881      |
| BMI kg/m <sup>2</sup> | r | -0.195        | 0.021         | -0.018      | -0.039     |
|                       | p | 0.033         | 0.818         | 0.843       | 0.671      |
| Pack Years            | r | -0.009        | -0.096        | -0.121      | -0.119     |
|                       | p | 0.927         | 0.320         | 0.209       | 0.217      |
| GOLD stage            | r | 0.098         | 0.226         | 0.091       | 0.154      |
|                       | p | 0.285         | 0.013         | 0.324       | 0.092      |

Reveal that the Table 2 predicted that the correlated of the other lung function parameters with HRQOL and found that FEV1/FVC was not significant, negative correlation with all three components of SGRQ score, FVC had significant negative correlation with SGRQ activity, impact and total score and insignificant negative correlation with symptom score, PEF had significant

negative correlation with activity and total score and insignificant negative correlation with symptoms and impact score.

No significant association was identified between HRQOL, GOLD staging, demographic variables such as age, body mass index and pack years of smoking.

## DISCUSSION

The present study was showed that 120 Indian patients with COPD had significantly impaired HRQOL as determined by disease specific questionnaire SGRQ. When examining specific domain of SGRQ, all showed impairment, however activity domain is most severely impaired. Lung functions as measured by FEV1 and classified as per GOLD criteria showed in the current study that the lower the FEV1, the lower the patient's HRQOL. Most of the previous studies, done in both Indian and western population, has shown similar results.<sup>13-18</sup> With worsening lung function, normal activity is limited or curtailed. All HRQOL domains appeared to be similarly impaired by the reduced FEV1. Authors have also correlated other lung function parameters (FEV1/FVC, FVC and PEF) with HRQOL; we found that most of these parameters had inconclusive correlation with HRQOL. Mostly previous studies have observed correlation of FEV 1 with HRQOL. There has been paucity of literature explaining relationship of other pulmonary function parameters with HRQOL.

This study has some limitations. It was a hospital-based survey and as such, the participants included in the study may be skewed towards the very sick patients. Patients often do not access health care in low resource settings until their clinical condition becomes very severe because of the cost of care. This potentially limits the ability to generalise the results of this study to all COPD patients. Also, majority of the patients in present study were males, therefore any generalisation of present results to women with COPD could not be done. Authors did not include patients with comorbidities in this study, which is very important predictor of HRQOL in COPD patients. Finally, most of the patients were illiterate in our study, patients required help from investigator to complete the SGRQ form, which might affect the results.

## CONCLUSION

Spirometry remains a core investigative modality in the management of COPD however it should be complemented with measures of quality of life. Indian patients with COPD show significantly reduced HRQOL as measured by disease specific questionnaire SGRQ, similar to COPD patients in other countries. All domains measured, including symptoms, activity, and impact, were impaired. In our study, only FEV1 % predicted was significantly correlated with HRQOL, all other measures including GOLD staging were not significantly associated with HRQOL. Future long term prospective studies, with larger number of patients, are needed to validate the results of the present study.

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