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Clinical profile of disease-causing chronic airflow obstruction in tertiary care centre in Lucknow

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ABSTRACT

Background: Chronic airflow obstruction (CAO) is a chronic lung condition that interferes with normal breathing. In common practice, CAO includes chronic obstructive pulmonary disease (COPD), asthma, chronic bronchitis, and emphysema. The present study was planned to be carried out in a tertiary care center to evaluate the profile of patients with chronic airflow obstruction with an aim to establish a cause-effect relationship between various disorders with chronic airflow obstruction. Aims and Objectives: The aim of the study was to find out the prevalence of different respiratory diseases among patients diagnosed as cases of chronic airflow obstruction and to evaluate the clinical and demographic profile of patients to find out risk factors and their role in etiology of chronic obstructive airflow. Materials and Methods: We studied demographic details of the patients, smoking history, biomass exposure, and tubercular history. All the patients were clinically examined and were subjected to pulmonary function assessment. The diagnosis of the patients was made on the basis of clinical features and outcome of spirometry. COPD was graded depending on post-bronchodilator FEV, % predicted as (GOLD, 2022). Results: Among patients with chronic airway obstruction, the number of patients diagnosed as COPD was highest (68%) followed by bronchial asthma (19%) and bronchectasis (13%). Among COPD population, 48% were smokers and 20% were non-smokers. Age of patients with bronchial asthma was significantly lower than that of other groups. In the present study, proportion of males diagnosed as COPD (NS) was significantly lower (P < 0.001) as compared to other groups. Conclusion: The findings in the present study highlighted that different types of CAO can affect a wide variety of population groups and share a number of risk factors; however, some demographic and clinical factors help in understanding the specific risks and type of disorder. A Change in environmental conditions and lifestyle can change the spectrum of CAO disorders.

Key words: Chronic airflow obstruction; Chronic obstructive pulmonary disease; Asthma; Chronic bronchitis; Emphysema; Spirometry

INTRODUCTION

Chronic airflow obstruction (CAO) is a chronic lung condition that interferes with normal breathing. In common practice, CAO includes chronic obstructive pulmonary disease (COPD), asthma, chronic bronchitis, and emphysema.1 The World Health Organization estimates that COPD is the fourth leading cause of death

worldwide (WHO, 2011) and predicts that it will soon become the third leading cause of death. While COPD, in general, includes both chronic obstructive bronchitis as well as emphysema, it excludes asthma or any localized cause of airways obstruction.^{2,3} Chronic airflow obstruction, that is persistent reduction in expiratory flow, is a characteristic feature of COPD and other obstructive respiratory disorders.4

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Risk factors clearly associated with CAO and a higher mortality from COPD include homozygosity for alpha antitrypsin deficiency, smoking, occupational exposure to certain dusts, lower socioeconomic status, and male gender.⁵ Other risk factors which may be important are air pollution, dietary antioxidant deficiency, and allergy and hyperresponsiveness. Smoking is generally regarded as the dominant cause of CAO but it is neither necessary nor sufficient.6 Some of the commonly identified environmental, occupational, personal, and opportunistic risk factors associated with CAO include smoke from biomass fuel, plant residues (wood, crops, twigs, and dried grass), animal residues (dung), and coal.7,8 Crop farming, animal farming, dust exposures, chemical exposures, and pollutant exposure might be the occupational risks. Smoking, treated pulmonary tuberculosis, lower respiratory tract infections during childhood, asthma, poor socioeconomic status, illiteracy, and lower educational status are some of the personal factors.9

The studies on undiagnosed airflow obstruction in a large sample of adults are very rare. Such studies, however, are important since identification of respiratory symptoms with associations with respect to undiagnosed airflow obstruction could lead to early intervention strategies that prevent or delay the onset of COPD and its disabling consequences. The present study was planned to be carried out in a tertiary care center to evaluate the profile of patients with chronic airflow obstruction with an aim to establish a cause-effect relationship between various disorders and chronic airflow obstruction.^{10,11}

Aims and objectives

This study aims to find out prevalence of different respiratory diseases among patients diagnosed as cases of chronic airflow obstruction and to find out risk factors and their role in etiology of chronic obstructive airflow.

MATERIALS AND METHODS

The present study was carried out at Department of Tuberculosis and Respiratory Medicine, Era's Lucknow Medical College, Lucknow, with an aim to evaluate the prevalence, spectrum, and clinical characteristics of chronic airflow obstruction patients. All the patients clinically diagnosed as having chronic airway obstruction fulfilling the following inclusion and exclusion criteria comprised the sampling frame of the study. Clinically diagnosed cases of chronic airway obstruction presenting with common complaints such as persistent cough, wheezing, respiratory difficulty, aged 10–70 years, and were clinically stable were included in the study. Patients having cardiac diseases, malignancies, and other systemic diseases suggestive of present clinical signs and symptoms, and patients unable to undergo spirometry or who did not agree to participate in the study were excluded from Demographic details of the patients, smoking history, biomass exposure, and tubercular history were noted. Anthropometric measurements were done to obtain BMI of the patients. All the patients were clinically examined and were subjected to pulmonary function assessment. The diagnosis of the patients was made on the basis of clinical features and outcome of spirometry.

Statistical analysis

To obtain the mean, the individual observations were first added together and then divided by the number of observations. Chi-square test was used to detect the correlation among observed frequency and expected frequency. To test the significance of two means the Student "t"- test was used. The ANOVA test was used to compare the within group and between group variances among the study groups. Analysis of variance of these three sealers at a particular time interval revealed the differences amongst them. P was considered to be level of significance. P>0.05 was not significant, P<0.05 was considered to be significant.

Ethical approval

The study was approved by the Institutional Ethics Committee. The EIC number was ELMC and H/2022/R_Cell/20151.

RESULTS

The present study was carried out at Department of Tuberculosis and Respiratory Medicine, Era's Lucknow Medical College, Lucknow, with an aim to evaluate the prevalence, spectrum, and clinical characteristics of chronic airflow obstruction patients. One hundred patients attending the OPD/admitted to the department were included in the study. They were clinically examined and were subjected to spirometry assessment. The diagnosis of the patients was made on the basis of clinical features and outcome of spirometry. On the basis of diagnosis, patients were grouped as under:

The number of patients diagnosed as COPD was highest in smokers (48%) followed by COPD (NS) (20%), bronchial asthma (19%), and bronchectasis (13%) (Table 1).

Difference in absolute values of FEV1 and FVC was found to be statistically non-significant before bronchodilation while after bronchodilation differences were statistically significant (Table 2a-c). Difference in absolute values of FEV1 and FVC was found to be statistically non-significant before bronchodilation while after bronchodilation differences were statistically significant.

No statistically significant difference among groups was observed for any of the parameters.

Grade of severity of COPD patients included ranged from II to IV. It was further analyzed whether Grade of COPD affected the treatment.

| Table 1: Distribution of patients according todiagnosis | | | | | | | | | |
|---|--------------------|------------|--|--|--|--|--|--|--|
| Group | Number of patients | Percentage | | | | | | | |
| COPD in smokers | 48 | 48.0 | | | | | | | |
| COPD in non-smokers | 20 | 20.0 | | | | | | | |
| Bronchial asthma | 19 | 19.0 | | | | | | | |
| Bronchiectasis | 13 | 13.0 | | | | | | | |
| COPD: Chronic obstructive nulmonary disease | | | | | | | | | |

Out of 48 patients diagnosed as COPD, 15 (31.25%) were graded as Grade II COPD, 26 (54.17%) were graded as Grade III COPD, and 7 (14.58%) were graded as Grade III COPD.

Pre-FEV1 and Post-FEV1 values of different grades of COPD showed statistically significant difference.

Pre-FVC and Post-FVC values of different grades of COPD patients showed statistically significant difference.

FEV1(Diff) and FVC(Diff) values of different grades of COPD patients did not show any statistically significant difference (Table 3a-c).

Pre-FEV1% and Post-FEV1% values of different grades of COPD showed statistically significant difference.

Pre-FVC% and Post-FVC% values of different grades of COPD patients showed statistically significant difference.

Table 2a: Spirometry (absolute values) – before and after bronchodilation

| Parameter | COPD (n=48) | | 48) COPD (NS) (n=20) | | Bronchial asthma (n=19) | | Bronchi-ectasis (n=13) | | Statistical significance (ANOVA) | |
|--------------------|-------------|------|-------------------------|------|----------------------------|------|---------------------------|------|-------------------------------------|---------|
| | Mean | SD | Mean | SD | Mean | SD | Mean | SD | F | Р |
| FEV1 abs (Pre) (I) | 1.09 | 0.35 | 1.09 | 0.43 | 1.35 | 0.55 | 1.11 | 0.45 | 1.882 | 0.138 |
| FEV1 abs (Post) | 1.17 | 0.36 | 1.13 | 0.39 | 1.72 | 0.58 | 1.14 | 0.40 | 9.413 | < 0.001 |
| FEV1 abs (Diff) | 0.12 | 0.10 | 0.14 | 0.15 | 0.37 | 0.16 | 0.12 | 0.09 | 19.799 | < 0.001 |
| FVC abs (Pre) | 2.05 | 0.57 | 2.01 | 0.62 | 2.32 | 0.85 | 2.06 | 0.62 | 0.976 | 0.407 |
| FVC abs (Post) | 2.12 | 0.52 | 2.00 | 0.63 | 2.86 | 0.84 | 1.95 | 0.54 | 9.056 | <0.001 |
| FVC abs (Diff) | 0.25 | 0.25 | 0.28 | 0.34 | 0.54 | 0.29 | 0.14 | 0.22 | 6.778 | <0.001 |

COPD: Chronic obstructive pulmonary disease, FEV: Forced expiratory volume, FVC: Forced vital capacity

| Table 2b: Spirometry (percent) – before and after bronchodilation | | | | | | | | | | | | |
|---|----------------|-------|------------------|-------|----------------------------|-------|-----------------------|-------|----------------------------------|--------|--|--|
| Parameter | er COPD (n=48) | | COPD (NS) (n=20) | | Bronchial asthma (n=19) | | Bronchiectasis (n=13) | | Statistical significance (ANOVA) | | | |
| | Mean | SD | Mean | SD | Mean | SD | Mean | SD | F | Р | | |
| FEV1% (Pre) | 39.38 | 12.54 | 41.10 | 14.51 | 45.42 | 18.10 | 41.23 | 14.46 | 0.805 | 0.494 | | |
| FEV1% (Post) | 42.40 | 13.27 | 42.25 | 11.76 | 58.42 | 20.27 | 42.23 | 12.46 | 6.323 | 0.001 | | |
| FEV1% (Diff) | 11.92 | 10.58 | 13.70 | 13.44 | 32.21 | 20.30 | 10.38 | 6.50 | 12.148 | <0.001 | | |
| FVC % (Pre) | 59.35 | 15.12 | 61.75 | 16.26 | 63.63 | 22.43 | 61.77 | 16.38 | 0.320 | 0.811 | | |
| FVC % (Post) | 61.77 | 15.10 | 60.85 | 13.80 | 79.53 | 23.99 | 58.54 | 13.67 | 6.388 | 0.001 | | |
| FVC % (Diff) | 12.25 | 10.84 | 13.75 | 14.07 | 27.47 | 18.36 | 6.38 | 7.72 | 8.576 | <0.001 | | |

COPD: Chronic obstructive pulmonary disease, FEV: Forced expiratory volume, FVC: Forced vital capacity

Table 2c: Spirometry (ii) FEV1/FVC – before and after bronchodilation

| • | • • • | | | | | | | | | (|
|---------------------|-------------|-------|------------------------------|-------|----------------------------|------|---------------------------|-------|-------------------------------------|-------|
| Parameter | COPD (n=48) | | COPD (n=48) COPD (NS) (n=20) | | Bronchial asthma (n=19) | | Bronchi-ectasis (n=13) | | Statistical significance (ANOVA) | |
| | Mean | SD | Mean | SD | Mean | SD | Mean | SD | F | Р |
| FEV1/FVC abs (Pre) | 53.38 | 8.16 | 53.59 | 8.28 | 57.51 | 6.64 | 53.12 | 8.23 | 1.393 | 0.250 |
| FEV1/FVC abs (Post) | 55.27 | 7.96 | 56.47 | 7.52 | 59.56 | 7.30 | 57.46 | 7.30 | 1.483 | 0.224 |
| FEV1/FVC abs (Diff) | 3.90 | 3.28 | 4.44 | 3.40 | 4.42 | 3.17 | 4.34 | 2.34 | 0.216 | 0.885 |
| FEV1/FVC % (Pre) | 68.73 | 10.49 | 68.90 | 10.60 | 73.26 | 8.54 | 68.69 | 10.06 | 1.015 | 0.390 |
| FEV1/FVC % (Post) | 71.25 | 10.50 | 72.50 | 9.53 | 76.11 | 9.85 | 74.46 | 8.94 | 1.200 | 0.314 |
| FEV1/FVC % (Diff) | 7.54 | 6.54 | 8.70 | 7.00 | 8.05 | 6.58 | 8.62 | 5.25 | 0.196 | 0.899 |
| | | | | | | | | | | |

COPD: Chronic obstructive pulmonary disease, FEV: Forced expiratory volume, FVC: Forced vital capacity

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| Table 3a: Spirometry (absolute values) – before and after bronchodilation in COPD patients | | | | | | | | | | | | |
|--|-------------------------|------|--------------------------|------|---------------|---------------|-------------------------------------|---------|--|--|--|--|
| Parameter | COPD Grade II (n=15) | | COPD Grade III (n=26) | | COPD G (n= | rade IV 7) | Statistical significance (ANOVA) | | | | | |
| | Mean | SD | Mean | SD | Mean | SD | F | Р | | | | |
| FEV1 abs (Pre) | 1.45 | 0.32 | 1.00 | 0.21 | 0.70 | 0.12 | 27.597 | <0.001 | | | | |
| FEV1 abs (Post) | 1.52 | 0.35 | 1.08 | 0.19 | 0.75 | 0.11 | 27.022 | < 0.001 | | | | |
| FEV1 abs (Diff) | 0.14 | 0.10 | 0.13 | 0.11 | 0.05 | 0.03 | 2.132 | 0.130 | | | | |
| FVC abs (Pre) | 2.46 | 0.62 | 1.93 | 0.45 | 1.58 | 0.32 | 9.012 | 0.001 | | | | |
| FVC abs (Post) | 2.47 | 0.54 | 2.04 | 0.42 | 1.65 | 0.35 | 8.523 | 0.001 | | | | |
| FVC abs (Diff) | 0.31 | 0.28 | 0.26 | 0.26 | 0.11 | 0.04 | 1.709 | 0.193 | | | | |

COPD: Chronic obstructive pulmonary disease, FEV: Forced expiratory volume, FVC: Forced vital capacity

Table 3b: Spirometry (percent) – before and after bronchodilation in COPD patients

| Parameter | COPD Grade II (n=15) | | COPD Grade III (n=26) | | COPD G (n= | rade IV 7) | Statistical significance (ANOVA) | |
|--------------|-------------------------|-------|--------------------------|-------|---------------|---------------|-------------------------------------|---------|
| | Mean | SD | Mean | SD | Mean | SD | F | Р |
| FEV1% (Pre) | 54.00 | 8.58 | 34.77 | 6.56 | 25.14 | 4.26 | 52.632 | <0.001 |
| FEV1% (Post) | 57.40 | 10.14 | 37.92 | 6.89 | 26.86 | 3.13 | 46.797 | <0.001 |
| FEV1% (Diff) | 10.67 | 8.24 | 13.73 | 12.51 | 7.86 | 5.34 | 1.002 | 0.375 |
| FVC % (Pre) | 73.87 | 13.54 | 54.62 | 10.66 | 45.86 | 7.27 | 19.716 | < 0.001 |
| FVC % (Post) | 74.47 | 13.76 | 58.15 | 11.93 | 48.00 | 8.31 | 13.875 | < 0.001 |
| FVC % (Diff) | 12.93 | 10.77 | 13.23 | 12.03 | 7.14 | 3.13 | 0.910 | 0.410 |

COPD: Chronic obstructive pulmonary disease, FEV: Forced expiratory volume, FVC: Forced vital capacity

Table 3c: Spirometry FEV1/FVC (absolute and percent) – before and after bronchodilation in COPD patients

| COPD Grade II (n=15) | | COPD Grade III (n=26) | | COPD Grade IV (n=7) | | Statistical significance (ANOVA) | |
|-------------------------|---|---|--|--|--|---|---|
| Mean | SD | Mean | SD | Mean | SD | F | Р |
| 59.38 | 6.39 | 52.19 | 6.97 | 44.94 | 6.67 | 11.806 | <0.001 |
| 61.91 | 5.81 | 53.79 | 6.31 | 46.52 | 6.60 | 16.332 | <0.001 |
| 3.80 | 3.23 | 4.16 | 3.18 | 3.15 | 4.08 | 0.265 | 0.768 |
| 77.27 | 8.03 | 66.88 | 8.38 | 57.29 | 8.30 | 15.375 | <0.001 |
| 80.53 | 7.62 | 69.12 | 8.11 | 59.29 | 7.18 | 19.617 | < 0.001 |
| 6.87 | 6.14 | 8.12 | 6.28 | 6.86 | 8.93 | 0.211 | 0.811 |
| | COPD G (n=1) 59.38 61.91 3.80 77.27 80.53 6.87 | COPD Grade II (n=15) Mean SD 59.38 6.39 61.91 5.81 3.80 3.23 77.27 8.03 80.53 7.62 6.87 6.14 | COPD Grade II (n=15) COPD G (n=2) Mean SD Mean 59.38 6.39 52.19 61.91 5.81 53.79 3.80 3.23 4.16 77.27 8.03 66.88 80.53 7.62 69.12 6.87 6.14 8.12 | COPD Grade II (n=15) COPD Grade III (n=26) Mean SD Mean SD 59.38 6.39 52.19 6.97 61.91 5.81 53.79 6.31 3.80 3.23 4.16 3.18 77.27 8.03 66.88 8.38 80.53 7.62 69.12 8.11 6.87 6.14 8.12 6.28 | COPD Grade II (n=15) COPD Grade III (n=26) COPD G (n= Mean Mean SD Mean Mean 59.38 6.39 52.19 6.97 44.94 61.91 5.81 53.79 6.31 46.52 3.80 3.23 4.16 3.18 3.15 77.27 8.03 66.88 8.38 57.29 80.53 7.62 69.12 8.11 59.29 6.87 6.14 8.12 6.28 6.86 | COPD Grade II (n=15) COPD Grade III (n=26) COPD Grade IV (n=7) Mean SD Mean SD 59.38 6.39 52.19 6.97 44.94 6.67 61.91 5.81 53.79 6.31 46.52 6.60 3.80 3.23 4.16 3.18 3.15 4.08 77.27 8.03 66.88 8.38 57.29 8.30 80.53 7.62 69.12 8.11 59.29 7.18 6.87 6.14 8.12 6.28 6.86 8.93 | COPD Grade II (n=15) COPD Grade III (n=26) COPD Grade IV (n=7) Statistical st (ANC (n=7) Mean SD Mean SD F 59.38 6.39 52.19 6.97 44.94 6.67 11.806 61.91 5.81 53.79 6.31 46.52 6.60 16.332 3.80 3.23 4.16 3.18 3.15 4.08 0.265 77.27 8.03 66.88 8.38 57.29 8.30 15.375 80.53 7.62 69.12 8.11 59.29 7.18 19.617 6.87 6.14 8.12 6.28 6.86 8.93 0.211 |

COPD: Chronic obstructive pulmonary disease, FEV: Forced expiratory volume, FVC: Forced vital capacity

FEV1%(Diff) and FVC%(Diff) values of different grades of COPD patients did not show any statistically significant difference.

A significant difference among different stages of COPD was observed for all the parameters except FEV1/FVC abs (Diff) and FEV1/FVC % (Diff).

Out of 20 patients diagnosed as COPD (NS), cause of COPD (NS) was post-TB treatment in 11 (55.0%) patients, cause of OPD was biomass exposure in 5 (25.0%) patients, and cause of OPD was occupational hazards in 4 (20.0%) patients.

DISCUSSION

The chronic airway obstructive (CAO) is a constellation of disorders having a different clinical course but have a common clinical manifestation and a variable burden of disease.¹² In the present study, we made an attempt to evaluate the prevalence, spectrum, and clinical characteristics of chronic airflow obstruction patients. For this purpose, a total of 100 patients attending the OPD/ admitted to the wards of Department of Tuberculosis and Respiratory Diseases, Era's Lucknow Medical College, Lucknow, were enrolled in the study and subjected to clinical and pulmonary function assessment. Among patients with different types of chronic airflow obstruction (CAO disorders – number of patients diagnosed as COPD was highest (48%) followed by COPD (NS) (20%), bronchial asthma (19%), and bronchectasis (13%).

In a previous study by Gothi et al., highlighting the profile of diseases causing chronic airflow limitation in a tertiary care center in India, bronchial asthma was the most common finding (63%) followed by COPD (17%), bronchiectasis (5%), and obstructive bronchitis (13%).¹³ In their series, 1% of patients were designated as having other causes. In a recent multicentric study, the prevalence of asthma and COPD has been reported to be 2.05% and 3.49%, respectively, with prevalence rates varying from center to center. Thus, the prevalence rates of COPD in this multicentric study were 1.7 times higher as compared to asthma whereas in the present study, the burden of bronchial asthma was much lower as compared to COPD with burden of COPD being 2.53 times higher as compared to that of bronchial asthma. One of the reasons for this could be increasing prevalence of COPD as well as high prevalence of smoking.^{14,15}

In the present study, mean age of patients with COPD (60.67 ± 6.64 years) followed by bronchiectasis (58.46 ± 9.02 years) and COPD (NS) (55.00 ± 10.67) was significantly higher as compared to that of patients with bronchial asthma (29.74 ± 4.78 years). The reason for this could be the fact that the prevalence of asthma in children has been reported to be 3–4 times higher.¹⁶⁻¹⁹ In a study by Gothi et al., (2007) too, the mean age of patients with bronchial asthma was found to be lower (38 years) than that of patients with COPD (54 years) and obstructive bronchitis (45 years).¹³

In the present study, smoking emerged as one of the most important and possibly the reason of chronic airflow obstruction (CAO diseases with 48/68 (70.6%) patients of COPD presenting with habit of smoking. Although smoking is regarded as the dominant cause of CAO, it is neither necessary nor sufficient. CAO may develop in lifelong non-smokers.¹⁸ The findings in present study agree with this proposition. Although majority cases of COPD (70.6%) were reported to be smokers yet for other diagnoses, the prevalence of smokers ranged from 0% (bronchial asthma) to 53.8% (bronchiectasis), thus underling the difference in epidemiology of chronic airflow obstruction diseases in India as compared to western world.

In a study, Behera and Jindal (1991) reported 13% of 3608 non-smoking women involved in domestic cooking had presence of respiratory symptoms.²⁰ Indoor exposure to domestic combustion especially the solid (or biomass) fuels such as the dried dung, wood, and crop residue is reported as an important cause of chronic bronchitis and COPD in women in studies from India, Nepal, China, South Africa, Turkey, and some other countries Incidentally, in the present study, out of a total of 11 women patients, nine were in COPD (NS) group and hence, biomass exposure emerged as a risk factor in this group only.²¹⁻²⁴

Although exposure to smoking was found to be present in post-tubercular patients only yet this association was not significant. The absence of smokers from among occupational hazardous group might be attributed to

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the prohibition of smoking at workplace in concerned industries. However, post-working hours, a tendency of smoking has been reported in these industries from some parts of the world yet they have not been associated with respiratory illness. Occupational hazard independently has a strong deteriorating effect on the respiratory system.^{25,26}

The findings in the present study thus specify that despite difference in impact and pathogenesis, the clinical presentation of the patients of chronic airway obstruction is overlapping and a confirmed diagnosis can only be established with the help of evaluation of pulmonary functions, detailed history taking, and laboratory evaluation.

Limitations of the study

Sample size was small, we can get better results with a larger sample size in future studies. The result of the study was limited to only Lucknow so in further studies we can include samples from all over India.

CONCLUSION

COPD is a complex condition, with many different components and mechanisms contributing to its pathophysiology and clinical presentation. Among the patients with chronic airway obstruction, COPD was highest followed by Bronchial asthma and lowest were the cases of bronchiectasis. Although asthma was the leading cause of CAO, it caused least degree of functional impairment. Smoking was an important etiology for COPD, while infectious disease including tuberculosis was the most common etiology for bronchiectasis.

Thus, the findings in the present study highlighted that different types of CAO can affect a wide variety of population groups and share a number of risk factors; however, some demographic and clinical factors help in understanding the specific risks and type of disorder. A change in environmental conditions and lifestyle can change the spectrum of CAO disorders. Thus, a detailed history of respiratory tract infection should be done and HRCT thorax should be sought for undiagnosed cases of CAO.

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AS- Concept and design of the study, review of literature, data collection, clinical protocol, and manuscript preparation; RS- Helped in the literature search and data collection and implementation of study protocol; and GS- Statistically analysed and interpreted data, helped in preparing first draft of manuscript, editing, and manuscript revision.

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