Research Article

Discordance between criteria-diagnosed and clinically-diagnosed asthma COPD overlap among hospitalized patients in an Indian referral hospital

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ABSTRACT

Background and Objectives: Asthma-chronic obstructive pulmonary disease-overlap (ACO), as a single entity, has been widely contested over the past few years. Most ACO diagnostic criteria do not agree with each other when applied to respiratory patients. From 2016 to 2020, Global initiative for asthma (GINA) described a syndromic approach for diagnosing ACO, which was replaced with a broader approach after 2021. We intended to learn if the GINA criteria and the chinese screening model for ACO (CSMA) screening tool agreed with a clinical diagnosis of ACO. **Materials and Methods:** We performed a retrospective cross-sectional analysis of inpatients with a clinical diagnosis of ACO from 2014 to 2019. We reclassified these patients into not-ACO and ACO using the GINA syndromic approach 2019 (GSA 2019), modified GSA 2019 (MGSA 2019), GINA 2021, and the CSMA tool. We used Kappa statistics to compare the performance of various tools. **Results:** Eighty-three clinically diagnosed ACO patients were included in the study. According to GSA 2019, only 41 (49.39%) patients would be classified as ACO. GINA 2021 picked up 57 (68.67%) patients as ACO. The modified GSA 2019, in which we proposed, identified 67 (80.72%) patients as ACO. The CSMA tool identified 63 (75.90%) patients as ACO. The GINA 2019 criteria, when interpreted liberally as described by us, have a better agreement with the CSMA tool with a sensitivity of 87.3% and specificity of 40%, with a "k" agreement of 29.3%. **Conclusion:** The standard GSA 2019 tool is stringent and may sometimes miss the ACO diagnosis. The original GSA table 2019 should be brought back with modifications.

Key words: *Asthma chronic obstructive pulmonary disease-overlap, Asthma chronic obstructive pulmonary disease overlap, Asthma chronic obstructive pulmonary disease overlap syndrome, Syndromic approach tool*

Asthma-chronic obstructive pulmonary disease-overlap (ACO), as a single entity, has been widely contested over the past few years. Even if it is not a unique disease such as asthma or chronic obstructive pulmonary disease (COPD), we now know that an individual can simultaneously have both asthma and COPD features [1]. A subset of COPD patients may have eosinophilic inflammation and will need corticosteroids. On the other hand, exposure to noxious stimuli in asthmatics can make the disease behave more like COPD, not responding to inhaled corticosteroids (ICS) [2,3].

Globally, 2% of the population is thought to have coexisting Asthma and COPD. About 27% of all asthma patients probably also have COPD; likewise, 30% of all COPD patients are estimated to have coexisting asthma [4] (We will refer to the presence of asthma and COPD in the same patient as "ACO" in this article as a merely descriptive term as suggested by global initiative for asthma (GINA) 2021). The prevalence of ACO differs based on the different criteria used [5]. Until 2019, GINA described a syndromic approach for diagnosing ACO, a detailed tool with 11 domains that include clinical features, spirometry and X-ray findings of COPD and asthma [4,5]. However, GINA 2021 has replaced the syndromic approach table with a broader approach comprising four main domains: clinical features, concurrent diagnosis of asthma, noxious stimuli exposure history, and a persistent airflow limitation in spirometry [6]. This change in GINA 2021 is likely due to a lack of agreement among clinicians and clarity on the exact implementation and interpretation of the GINA syndromic approach 2019 (GSA 2019).

Researchers from China used a practical approach to address this conundrum and devised the "Chinese Screening Model for ACO (CSMA) Tool," a short questionnaire to screen ACO. Zhou *et al*. surveyed numerous pulmonologists as to what they thought were clinical features of ACO and, based on the data they collected, developed the CSMA tool [7]. CSMA is the first pragmatic diagnostic tool that clinicians developed.

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Table 1: Reclassification of diagnosis (total Patients=83)

Criteria	Not-ACO			ACO	Unclassifiable
	Asthma	COPD	Total		
GSA 2019	19	23	42	41	0
GSA 2021	12	0	12	57	14
MGSA 2019	6	10	16	67	0
CSMA tool			20	63	0

MGSA: Modified GINA syndromic approach 2019, CSMA: Chinese screening model for ACO

We believe that a lenient way of implementing the GINA 2019 Syndromic approach would be better than the GINA 2021 recommendations. We wanted to know if GINA diagnostic criteria and the CSMA tool agree with expert clinical assessment, in diagnosing ACO. We selected a population of patients already diagnosed as ACO by experts and applied the GINA criteria in three different ways and the CSMA tool to see which was better.

MATERIALS AND METHODS

We performed a retrospective analysis of all admissions with a physician-made clinical diagnosis of ACO or asthma COPD overlap syndrome (ACOS) from 2014 to 2019. At least three doctors from the Department of Pulmonary Medicine arrived at the diagnosis together based on a thorough clinical evaluation during the hospital admission. The Institutional Review Board of the medical College approved the study.

We applied three different forms of GINA criteria and the CSMA tool to the study population with which we reclassified these patients into not-ACO (Asthma, COPD) and ACO:

1. The GSA 2019,
2. MGSA 2019,
3. GINA 2021 and
4. The CSMA tool.

There are no data on the true prevalence of criteria-diagnosed ACO in a clinically diagnosed ACO population. Furthermore, we found very few admissions with a diagnosis of ACO over the years. Hence, we included all patients who fulfilled our inclusion criteria. Our inclusion criterion was patients diagnosed with ACO without other chronic respiratory diseases.

The GSA 2019 is an eleven-part table describing 11 features of asthma and COPD. Usually, if there are a similar number of COPD and asthma features, ACO is diagnosed. We also used a new method of interpreting the GINA 2019, referred to further as "MGSA 2019. Here, we considered a diagnosis of ACO if more than three features favour asthma and COPD, irrespective of the difference in the number of features favouring one over the other. For example, if six points are for Asthma and three favour COPD, both have more than three favouring characteristics; hence, the presence of both "Asthma and COPD" would be considered.

According to GINA 2021, to diagnose ACO, the pattern of symptoms should overlap between asthma and COPD, along with a current or past diagnosis of asthma, exposure to noxious stimuli and a persistent airflow limitation in spirometry. The CSMA screening tool has eight criteria – six clinical queries and two spirometry values. A score of 6 or above favours a diagnosis of ACO [7].

General demographic information, clinically made physician diagnosis, treatment details, spirometry data, and X-ray findings of the study population were obtained from electronic medical records. Pack-years was used to quantify smoking, and BMF-index was used for biomass fuel exposure [8]. Data entry was done using Epi Info 7, and results were analyzed using STRATA. The Chi-square test and paired t-test were used to calculate statistical significance in categorical and continuous variables, respectively. We used Kappa statistics to compare various tools.

RESULTS

The diagnosis of ACO increased in frequency over the years. There have been 83 admissions since 2014 with a diagnosis of ACO/ACOS. Before 2017, there were only 14 admissions with an ACO diagnosis, compared to 69 after 2017.

- Characteristics of the clinically diagnosed ACO population:

The mean age of the study population was 61.30 (±9.485) years, with a minimum of 38 years and a maximum of 82 years. Forty-eight (67.8%) patients were male, and 35 (42.2%) were female. Thirty-eight (45.8%) patients were labelled as probable-ACO, whereas 45 (54.2%) were confidently labelled as ACO. Only 12 (14.5%) patients had a positive family history of asthma. Overall, 46 (55.4%) patients had a positive smoking history with 27.89 (±15.71) pack years. Similarly, 34 (41%) patients had significant exposure to biomass fuels, with a mean BMF index: 47.79 (±47.37). The most common comorbidities were diabetes (53.6%), hypertension (44.6%), and obstructive sleep apnea (34.9%). Overall, 39 (46.9%) patients had type 2 respiratory failure, and 13 (15.7%) patients had type 1 respiratory failure. Except for 14 patients who could not perform spirometry, all other patients had an obstruction in spirometry. Among those with spirometry, 17% had a moderate obstruction, and 63% had a severe obstruction. The mean serum IgE level was 730±420 IU for the entire population. The mean hospital admissions each year per ACO patient was 1.47 (±1.4). Our study population's overall in-hospital mortality rate was 2.4% (2 patients).

- After applying the various diagnostic criteria to the study population:

The original clinician-diagnosed ACO population was reclassified using the four criteria described earlier into "ACO" and "not-ACO" patients. According to GSA 2019, only 41 (49.39%) patients would be classified as ACO. GINA 2021 picked up 57 (68.67%) patients as ACO (Table 1). Fourteen patients could not perform spirometry due to poor respiratory effort. Since spirometry is an essential criterion for diagnosing ACO as per GINA 2021, 14 patients could not be classified as ACO or COPD despite having clinical features of asthma and COPD. The modified GSA 2019, in which we proposed, identified 67 (80.72%) patients as ACO. Despite the lack of spirometry in 14 patients, the CSMA tool identified 63 (75.90%) patients as ACO.

Table 2: Comparison of ACO and Not-ACO after reclassification based on GINA syndromic approach 2019

Characteristics	Not ACO (n=42)	ACO (n=41)	p-value
Sex			
Male=48	24	24	0.898
Female=35	18	17	
Age (Mean)	62.07	60.51	0.457
Follow-up			
Regular before and after admission (n)	11	13	0.263
Regular after admission	15	11	0.385
Not regular	16	17	0.755
Risk factors			
Family history of asthma (n)	7	5	0.564
Smoking (n)	21	25	0.317
Pack years	32	25	0.247
BMF exposure (n)	19	15	0.425
BMF index	42	55	0.461
Comorbidities			
Interstitial lung disease (n)	1	2	0.545
Carcinoma lung (n)	3	1	0.319
Cor pulmonale (n)	8	4	0.231
Pulmonary hypertension (n)	11	6	0.194
Cor pulmonale or pulm HTN (n)	19	10	0.047
Obstructive sleep apnoea (n)	14	15	0.757
Cardiovascular diseases (n)	10	9	0.842
Past history of tuberculosis (n)	5	1	0.097
Allergic rhinitis (n)	14	11	0.520
Diabetes mellitus (n)	24	18	0.230
Systemic hypertension (n)	21	16	0.317
Acid peptic disease (n)	8	4	0.231
Psychiatric conditions (n)	1	0	0.323
Anxiety disorder (n)	2	0	0.159
Hyperinflation in X-ray (n)	19	22	0.445
Spirometry			
FEV1/FVC <0.7 (n)	28	29	0.322
Mild obstruction (FEV1 >80) (n)	3	0	0.059
Moderate obstruction (FEV1 50–80) (n)	3	11	0.036
Severe obstruction (FEV1 <50) (n)	26	26	0.294
Mean reversibility (%)	20.97	20.32	0.867
Mean volume of reversibility (mL)	148	167	0.496
Mean immunoglobulin E (IU/L)	317.9 (8 out of 42)	977 (15 out of 41)	0.282
Mean absolute eosinophil counts (Number)	274 (27 out of 42)	350 (32 out of 41)	0.337
ABG			
pH	7.36	7.36	0.950
pCO_2 (mmHg)	53.8	53.7	0.987
pO_2 (mmHg)	73.8	73.5	0.943
Respiratory failure			
No (n)	15	16	0.756
Type 1 (n)	8	5	0.393
Type 2 (n)	19	20	0.747
Treatment			
IV steroids (n)	23	18	0.209
Oral steroids (n)	26	22	0.449

(Contd...)

Table 2: (*Continued*)

Characteristics	Not ACO (n=42)	ACO (n=41)	p-value
Dose of steroids (mean)	491	434	0.305
IV Antibiotics (n)	11	11	0.948
Oxygen supplementation (n)	23	16	0.153
NIV support (n)	16	17	0.755
Intubations (n)	0	1	0.312
Number of admissions per year (mean)	1.67	1.27	0.398
ICU admissions (n)	3	1	0.319
In-hospital mortality (n)	2	0	0.159
Treatment step before admission			
GINA 1	18	20	0.590
GINA 2	1	2	0.545
GINA 3	10	6	0.292
GINA 4	7	1	0.029
GINA 5	6	12	0.099
Treatment step after discharge			
GINA 1	0	0	-
GINA 2	0	0	-
GINA 3	2	1	0.571
GINA 4	2	3	0.627
GINA 5	38	37	0.971
CSMA screening tool			
ACO	30	33	0.335
Not ACO	12	8	

CSMA: Chinese screening model for ACO, NIV: Non-invasive ventilation, FVC: Forced vital capacity, FEV1: Forced expiratory volume in 1 s, GINA: Global initiative for asthma

- Comparison of ACO and not-ACO diagnosed with GSA 2019:

As per GSA-2019, 42 patients were classified as not-ACO and 41 patients as ACO. Most patient characteristics, including demographics, risk factors, comorbidities, and X-ray findings, were similar between ACO and not-ACO (Table 2). Cor pulmonale and pulmonary HTN were common in the not-ACO group compared to ACO group (19 [45.23%] vs. 10 [24.39%] [p=0.0478]). ACO patients had a lower mean dose of steroid intake in the current admission compared to not-ACO patients (434 vs. 491 [p=0.305]). A difference of 57 mg is not statistically significant, but it is clinically relevant.

- Comparison of ACO and not-ACO diagnosed with MGSA 2019.

Using the MGSA 2019 tool, 67 patients were classified as ACO and 16 patients as not-ACO. The not-ACO group had more cor pulmonale and pulmonary hypertension than ACO. All other findings were similar between the two groups without any statistical significance.

Performance of CSMA Tool as a Screening Test

When GSA 2019 was considered the gold standard for ACO diagnosis, then the CSMA Tool's sensitivity was 52.4%, and specificity was 60%, with a poor k agreement of 9%. However, if the modified GINA tool was the gold standard, then the CSMA Tool's sensitivity improved to 87.3%, and specificity dropped to 40%, with a "k" agreement of 29.3%. Since the sample size is small, the kappa statistical significance may not be accurate. Nevertheless, an improvement of k value from 9% to 29% on modifying the GSA 2019 suggests that the CSMA tool agrees more with the modified GINA tool.

DISCUSSION

Differentiating severe asthma, severe COPD, and ACO can be difficult when a patient presents to us with exacerbation. In asthma, with disease progression, the behaviour of the disease is similar to COPD or ACO [9]. Asthma's behaviour as COPD or ACO could be due to genetic variation in the type of inflammation or exposure to noxious stimuli [2,3,10,11]. Asthma can have either an eosinophil-rich inflammation in the airway or, occasionally, a neutrophil-dominant inflammation. The presence of more neutrophils is associated with corticosteroid resistance, like COPD [12]. Hence, tools such as the GINA global initiative for chronic obstructive lung disease (GOLD) syndromic approach table, with more clinical weightage, are essential in helping the clinician delineate the disease's clinical behaviour accurately.

When ACO was initially described, earlier studies reported worse outcomes in ACO compared to asthma or COPD. The PUMA study reported 2.68 exacerbations per year for ACO, compared to 1.85 exacerbations per year for Asthma. ACO had

more exacerbations than COPD as well [13]. ACO patients were reported to have worse baseline mMRC grade of breathlessness compared to asthma [14]. Meta-analysis and systematic reviews have reported a higher number of exacerbations, increased respiratory morbidity, and high prevalence of comorbidities such as diabetes in ACO compared to COPD and asthma [15,16]. ACO patients tend to have worse quality of life than COPD or Asthma [17,18].

However, in the past few years, with more studies on ACO, it is now established that ACO has a better outcome and morbidity profile than COPD. The CHAIN study, in 2016, confirmed that ACO had a lower BODE index and mortality rate at 1-year follow-up than COPD [19]. An extensive retrospective analysis done in Japan revealed that the inpatient mortality rate was highest for COPD (9.7%), followed by ACO (2.3%) and then asthma (1.2%) [20]. ACO had poor outcomes compared to asthma, but COPD was worse of the three [21-23].

In our study, we found that the number of exacerbations per year (1.67 vs. 1.27), need for ICU care (7.14% vs. 2.43%), inpatient mortality(4.7% vs. 0), and mean steroid dose (491mg vs. 434mg) in the current admission – were all higher in the criteria-diagnosed not-ACO group compared to the criteria-diagnosed ACO group, though not statistically significant. This is despite the ACO group having the same number of patients with severe disease as the not-ACO group. Most studies report a higher prevalence of hyperinflation in X-ray among ACO patients [24]. We found a similar prevalence of hyperinflation in ACO and not-ACO patients.

After reclassification, no statistically significant difference was found in any parameter in the criteria-diagnosed ACO group versus not-ACO group. The above findings imply that the clinical diagnosis of ACO did identify a homogenous population with similar characteristics. If the clinical diagnosis is considered the gold standard for diagnosing ACO, both GSA 2019 and the CSMA have failed to identify 56% and 24% of actual ACO patients. MGSA 2019 misses 19.3% of clinically diagnosed ACO patients.

Is the concept of ACO relevant today? The GOLD 2021 document has stated that the term ACO is no longer valid. GINA 2020 has omitted the syndromic approach table altogether but still allows the term to be used as a descriptor. Asthma and COPD in the same patient is possible, with both disease processes having different severity levels. If COPD is dominant, disease behaviour tends to be worse. Whereas if asthma symptoms are dominant, the patient could have better outcomes. The GINA GOLD guidelines do advise treatment for both COPD and the asthma component [1,25].

ICS are indicated only in group-D COPD when there is evidence of eosinophilic inflammation [1]. Mislabelling ACO as COPD can seriously impact patients' health when preventable. Avoiding ICS in the early ACO will lead to disease progression, which is preventable if the diagnosis was made correctly. It is necessary to consider using the term asthma COPD overlap to help clinicians understand the necessity to look for both diseases in all patients.

When GINA and GOLD introduced the syndromic approach table to help clinicians diagnose ACO, there were plenty of other tools to diagnose ACO. GINA 2019 syndromic approach tool (SAT) was a comprehensive tool but had some practical difficulties in application and interpretation. Based on the original SAT, ACO should be diagnosed only if there are equal features favouring both asthma and COPD. However, the disease characteristics of patients with near-equal features (Ex: 3 and 4 or 5 and 4) are often similar to ACO, rather than asthma or COPD. Hence, we attempted a liberal interpretation of GINA tool (Referred to as Modified GINA Tool in this article) to capture these borderline patients in our study. The modified GINA-GOLD tool classified 80% of the clinically-diagnosed-ACO patients as ACO. The modified tool had a better agreement with the CSMA tool as well (kappa 0.29).

CONCLUSION

Among patients who were clinically diagnosed to have both asthma and COPD, the GSA 2019 confirmed the diagnosis of overlap in 49.39%. Using the modified GINA tool, the prevalence was 80.72%. Using both criteria, after reclassification, the characteristics of ACO and Not-ACO were very much similar. This could be the reason why clinicians labelled all these patients as ACO. The CSMA screening test for ACO did correlate better with the modified GINA tool. The standard GSA 2019 tool is stringent and may miss the ACO diagnosis in some instances. The original GSA table 2019 should be brought back with modifications.

DATA AVAILABILITY

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

CONTRIBUTION DETAILS

Jefferson Daniel, Barney Isaac and Devasahayam J Christopher conceived and designed the study. Jefferson Daniel acquired the data. Jefferson Daniel, Barney Isaac and Devasahayam J Christopher performed the analysis and interpretation of data. Jefferson Daniel drafted the article. Barney Isaac and Devasahayam J Christopher revised it critically for important intellectual content. Jefferson Daniel, Barney Isaac and Devasahayam J Christopher approved the version to be published.

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