COVID-19 Vaccination Status among Patients with Chronic Respiratory Diseases: A Cross-sectional Study from a Tertiary Care Centre in Southern India

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ABSTRACT

Introduction: Pre-existing respiratory diseases were recognised as risk factors for COVID-19 associated morbidity and mortality. One year after the launch of vaccines against COVID-19, vaccination status in specific population was not clear. Vaccination of population at risk is crucial for COVID-19 control.

Aim: To estimate the COVID-19 vaccination status and to detect the reasons for vaccine hesitancy among people with chronic respiratory diseases.

Materials and Methods: This cross-sectional observational study was conducted in Respiratory Medicine Department at Narayana Medical College, Nellore, Andhra Pradesh, India, from January 2022 and February 2022. All the patients above 18 years of age, who presented with chronic respiratory diseases, were included in the study. After taking informed consent, their responses were noted using a validated questionnaire containing data like demographic data and details of vaccination against COVID-19 and reasons for refusal/hesitancy.

Results: Out of total 755 subjects, 44.50% were of Chronic Obstructive Pulmonary Disease (COPD), 42.38% were of asthma, 9.40% were of Post-tuberculosis lung disease, 2.52% were of bronchiectasis, and 1.72% were of Interstitial Lung Disease (ILD). Mean age of study population was 51.37±15.30 years, 58% were male and 42% were female. Overall, 75% subjects received atleast single dose of COVID-19 vaccine. Higher vaccine acceptance was noted among 31-42 years age group, males, residents of rural area, graduates, subjects with income more than one lac per month and smokers. Vaccine hesitancy was 25%. Intake of a native medicine (72.87%) was the most common cause for vaccine refusal among these subjects. Other reasons for vaccine hesitancy were, worries about side-effects (63.3%), associated multiple co-morbidities (44.15%), lack of confidence in vaccines (15.96%) and fear of injection (14.89%).

Conclusion: Vaccine acceptance against COVID-19 is nearly 75% among people with chronic respiratory diseases in India. Nonetheless, some people were still hesitant to receive vaccine. Continuous health education at every level is needed to achieve vaccination targets.

INTRODUCTION

Irrespective of health standards being followed, COVID-19 pandemic adversely affected the lives of millions of people around the world during last 2 years. India, being a Southeast Asian country with dense population, was one of the most affected countries on the globe [1]. By 28th February 2022, there have been 434,154,739 confirmed cases of COVID-19 and 5,944,342 deaths across the globe of which 42,924,130 cases and 5,13,843 deaths were from India [2]. Vaccination against COVID-19 became one of the rays of hope in this desperate situation inspite of many preventive measures [3]. Though a number of vaccines were rolled out in various countries, India faced several challenges during mass vaccination program starting from availability to acceptability [4].

The COVID-19 vaccine acceptance was highly variable across countries ranging from 15.4% to 97% [5,6]. India being a diversified country, various regional and population wise differences were expected towards the mass vaccination [4]. Available evidence suggests that patients with chronic respiratory disease were at increased risk of morbidity and mortality during COVID-19 [1,7]. Of the total global Disease Adjusted Life Years (DALYs) due to chronic respiratory diseases in 2016, 32.0% occurred in India [8]. Chronic Obstructive Pulmonary Disease (COPD) is the most common disease among chronic respiratory diseases [9]. Nearly 65 million moderate to severe COPD patients are there globally and COPD accounts for 5% (41.9 per l lakh) of total deaths annually [9]. Chronic respiratory diseases constitute 10.9% of total deaths and 6.4% of total DALYs in India in 2016 [8]. In India, the crude prevalence of COPD was 4.2%, and asthma was 2.9% in 2016 [8]. In India, COPD and asthma were responsible for 75.6% and 20.0% of the chronic respiratory disease DALYs, respectively, in 2016 [8]. COPD is responsible for 8.7% of total deaths and 4.8% of total DALYs in India [8]. Asthma is responsible for 1.9% of total deaths and 1.3% of total DALYs in India [8]. In 2016, the DALYs per patient of COPD and asthma were 1.7 and 2.4 times higher in India than the global average, respectively. The crude case fatality rates of COPD and asthma are 1.53% and 0.48% in India.

Interstitial Lung Disease (ILD) constitute 0.28% of total deaths and 0.14% of total DALYs in India [8]. Overall, 39% of mortality is from COPD among chronic respiratory diseases [9], 66% of COPD mortality is in India and China [9]. Approximately 50% survivors of Pulmonary Tuberculosis (PT) develop Post-tuberculosis Lung Diseases (PTLD), like parenchymal cavitation, bronchitis, fibrotic alteration, and bronchiectasis. Adult PT survivors have a 2-4 fold increase in spirometry abnormalities and have a 3-fold increased risk of death. Worldwide 58 million PTLD were present [10]. The prevalence of non cystic fibrosis bronchiectasis in high-income countries (566 per 1 lakh population). But data from low and middle-income countries is not consistent [10].

Prevalence of respiratory co-morbidities in COVID-19 was 1.5-17.7% (non asthmatics) and 14.5% asthmatics [11]. In South Africa, 10% of COVID-19 had current or past tuberculosis [12]. PTLD with persistent pulmonary impairment are more susceptible to COVID-19 and increased mortality with COVID-19 [12]. COVID-19 mortality rate was 1.54% in India, as on 24th March 2021 [11]. COVID-19, when associated with concurrent or past PT, hospital-based mortality increased by two times [12]. Hence these people are a priority for earlier Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) vaccination. Even among survivors of COVID-19 with underlying PTLD, increased chance of long COVID-19 or lung disease after COVID-19 [12]. Vaccination against COVID-19 in this group of people is not only crucial for ending the pandemic but also essential for restoring tuberculosis services [12]. Hence, this study was aimed to assess COVID-19 vaccine coverage and reasons for vaccine hesitancy among people with chronic respiratory diseases.

MATERIALS AND METHODS

This cross-sectional observational study was conducted in Respiratory Medicine Department at Narayana Medical College, Nellore, Andhra Pradesh, India, from January 2022 and February 2022. Institutional Ethics Committee approved the study protocol (IEC/NMC/02/02/2022_4).

Sample size estimation: The estimated sample size was 539 with the prevalence of vaccine acceptance (66%) against COVID-19 in India [1], 95% of confidence and 4% of precision.

Inclusion criteria: All subjects above 18 years of age with chronic respiratory diseases, who visited the study institution during the study period, were included in the study.

Exclusion criteria: Patients who had acute respiratory symptoms, and patients who failed to show their vaccination certificates were excluded from the study. Incompletely filled questionnaires were also excluded.

Questionnaire

A questionnaire was used to collect data. It was developed in English language by investigators of the study. It comprised of two sections:

- **First section:** Socio-demographic details of patients like name, age, gender, education, occupation, marital status, place of residence, smoking status, presence or absence of chronic respiratory disease, name of disease, any co-morbid condition, type of co-morbidity and previous COVID-19 infection.

- **Second section:** Details of vaccination against COVID-19 and reasons for refusal/hesitancy.

The questionnaire was validated through a pilot study among 20 patients. The data was excluded during the final analysis.

All participants were explained clearly about the confidentiality, purpose and procedure of the study. After taking informed consent, each participant was interviewed in person without affecting their privacy and the questions were explained in their local language. The self-reported responses to the questionnaire was collected.

Study subjects were stratified into Asthma, COPD, Bronchiectasis, ILD, and Pulmonary Tuberculosis (PT) sequelae based on their clinical history, physical examination, chest imaging and spirometry. Participants who claimed vaccinated status, but failed to show vaccination certificate, were excluded from the study. Those who did not receive single dose of a vaccine were inquired about reasons for doing so and their responses were noted.

STATISTICAL ANALYSIS

Data were analysed by Statistical Package for Social Sciences (SPSS) IBM, version 28.0. Continuous variables like age were expressed as mean and standard deviation. Categorical variables like socio-demographic parameters, smoking status, co-morbidities, chronic respiratory condition, and previous COVID-19 were expressed as

numbers and percentages. Relation between categorical variables and the vaccination status was analysed using Chi-square test. A p-value <0.05 was considered as significant.

RESULTS

A total of 802 eligible subjects were identified. Of them, 47 participants were excluded for not showing vaccination certificates. Finally, 755 participants' data were analysed. Mean age of study population was 51.37±15.30 years and males were 438 (58%). Demographic characteristics were displayed in [Table/Fig-1]. They were stratified

Vaccination status against COVID-19				
Variables	Total number	Acceptance	Hesitancy/ Rejection	p-value
Age group (years)				
18-30	76 (10.07%)	54 (71.1%)	22 (28.9%)	
31-42	147 (19.47%)	117 (79.6%)	30 (20.40%)	
43-54	199 (26.36%)	147 (73.9%)	52 (26.1%)	0.639
55-66	203 (26.88%)	153 (75.4%)	50 (24.6%)	
>66	130 (17.21%)	96 (73.8%)	34 (26.2%)	
Gender				
Male	438 (58%)	333 (76.02%)	105 (23.97%)	0.488
Female	317 (42%)	234 (73.81%)	83 (26.18%)	
Marital status				
Married	567 (75%)	426 (75.13%)	141 (24.86%)	
Unmarried	80 (10.5%)	66 (82.5%)	14 (17.5%)	-
Widow/divorced	108 (14.5%)	75 (69.44%)	33 (30.55%)	
Residence				
Urban	253 (33.50%)	192 (75.88%)	61 (24.11%)	
Suburban	229 (30.33%)	166 (72.48%)	63 (27.51%)	0.541
Rural	273 (36.15%)	209 (76.55%)	64 (23.44%)	
Education				
Professional	42 (5.56%)	30 (71.42%)	12 (28.57%)	
Graduation	138 (18.27%)	108 (78.26%)	30 (21.73%)	
Intermediate/ diploma	190 (25.16%)	144 (75.78%)	46 (24.21%)	0.361
High school	265 (35.09%)	203 (76.60%)	62 (23.39%)	
Middle school or less	120 (15.89%)	82 (68.33%)	38 (31.66%)	
Income (per month)				
<18000	50 (6.62%)	31 (62%)	19 (38%)	
18,001-35,000	192 (25.43%)	146 (76.04%)	46 (23.95%)	
35,001-60,000	311 (41.19%)	235 (75.56%)	76 (24.43%)	0.213
60,001-1,00,000	182 (24.10%)	138 (75.82%)	44 (24.17%)	
>1,00,000	20 (2.64%)	17 (85%)	3 (15%)	
Smoking status				
Exposure to smoking	439 (58.14%)	336 (76.53%)	103 (23.46%)	0.281
No exposure to smoking	316 (41.85%)	231 (73.10%)	85 (26.89%)	
Co-morbidities				
Present	565 (74.83%)	425 (75.22%)	140 (24.78%)	0.894
Absent	190 (25.17%)	142 (74.74%)	48 (25.26%)	
Previous COVID-19				
Yes	284 (37.61%)	214 (75.35%)	70 (24.64%)	0.457
No	471 (62.38%)	353 (74.94%)	118 (25.05%)	
Number of vaccine doses received				
2	439 (58.15%)			
1	128 (16.95%)			
0	188 (24.90%)			

[Table/Fig-1]: Socio-demographic characteristic features of study population.
*p-value <0.05 was considered as significant

into COPD, asthma, PT sequelae, bronchiectasis and ILD. Further subgroup analysis of chronic respiratory diseases and vaccine acceptance were mentioned in [Table/Fig-2].

Disease	Total (755)	Acceptance	Hesitancy/Rejection	p-value
COPD				
Yes	336 (44.50%)	260 (77.38%)	76 (22.62%)	0.194
No	419 (55.50%)	307 (73.27%)	112 (26.73%)	
Asthma				
Yes	319 (42.38%)	236 (73.98%)	83 (26.02%)	0.543
No	436 (57.62%)	331 (75.92%)	105 (24.08%)	
PTLD				
Yes	71 (9.4%)	49 (69.01%)	22 (30.99%)	0.213
No	684 (90.6%)	518 (75.73%)	166 (24.27%)	
Bronchiectasis				
Yes	19 (2.52%)	14 (73.68%)	5 (26.32%)	0.885
No	736 (97.48%)	553 (75.14%)	183 (24.86%)	
ILDs				
Yes	10 (1.72%)	8 (80%)	2 (20%)	0.718
No	745 (98.28%)	559 (75.03%)	186 (24.97%)	

[Table/Fig-2]: Vaccination status among patients with chronic respiratory diseases. COPD: Chronic obstructive pulmonary disease; PTLD: Post-tuberculosis lung disease; ILD: Interstitial lung disease. p-value <0.05 is significant

The overall prevalence of COVID-19 vaccine acceptance among study participants was 75%, significantly higher than vaccine hesitancy (25%) [Table/Fig-1]. On subgroup analysis, higher COVID-19 vaccine acceptance among participants with chronic respiratory diseases were noted among men (76%), 31-42 years age group (79.6%), unmarried people (82.5%), rural dwellers (76.55%), graduates (78.26%), subjects with income more than one lakh per month (85%), smokers (76.5%).

The reasons for vaccine refusal includes reception of a native medicine, having multiple co-morbidities, concerns about unforeseen side-effects, lack of confidence, and afraid of injection. The association between descriptive parameters and vaccine status among the study participants was not statistically significant (p-value >0.05) [Table/Fig-3].

Reason	n, %
Intake of a native medicine	137 (72.87%)
Concerns about side-effects	119 (63.3%)
Multiple co-morbidities	83 (44.15%)
Lack of trust	30 (15.96%)
Fear of injection	28 (14.89%)

[Table/Fig-3]: Vaccine hesitancy against COVID-19 (n=188)*.
*Some patients mentioned more than one cause

DISCUSSION

In India, vaccination against COVID-19 rolled out in a stepwise manner. Initially, healthcare workers/frontline workers followed by people above 60 years of age or above 45 years with multiple co-morbidities. COVID-19 has severely affected individuals with co-morbid conditions. When these people also have chronic respiratory diseases, risk of COVID-19 morbidity and mortality increases many folds [1]. Vaccination of at-risk populations is a crucial step in achieving herd immunity. Hence, vaccine allocation policies have prioritised these people. Some previous studies assessed acceptance of vaccines against COVID-19 in countries like the United States of America (USA), Saudi Arabia, India, China, and Ethiopia. The following [Table/Fig-4] depicts the details of these studies.

These studies took place from April 2020 to May 2021. Some of them occurred even before the rollout of any vaccine [13,14]. And some other studies were conducted during the 2nd wave of COVID-19 in respective countries [15-17]. The majority of the studies

Place of study	Time of study	Study population	Vaccine acceptance	Top reasons for vaccine refusal
USA [13]	April-May 2020	African Americans recovered from COVID-19 (n=119)	30%	Lack of trust on vaccines. Concerns about side-effects. Perceived immunity against future SARS-CoV-2 infection.
Saudi Arabia [14]	December 2020	Chronic diseases (n=521)	270 (51.82%)	Less education. Female gender. No previous flu vaccination.
Multi-national [18]	January-February 2021	Multiple co-morbidities (n=21,943)	81%	Lack of trust. Concerns about vaccine safety. Want to watch vaccine response in others.
Saudi Arabia [19]	February-March 2021	Chronic diseases (n=310)	51.95%	Concerns about side-effects. Preventive measures are sufficient. Vaccine will not prevent the infection.
India [15]	March-April 2021	Autoimmune rheumatic disease (n=280)	152 (54%)	Not yet decided. No need of vaccination. Concerns about side-effects.
China [16]	March-May 2021	Chronic diseases (998)	70.6%	Physical reasons. Concern about side-effects. Watching the impact of vaccine on others.
Ethiopia [17]	May 2021	Chronic diseases (n=416)	247 (59.4%)	Concerns about side effects. Lack of trust. Previous vaccine apathy.
Present study	January-February 2022	Chronic respiratory diseases (n=755)	567 (75%)	Intake of a native medicine. Concerns about side-effects. Having multiple co-morbidities.

[Table/Fig-4]: Studies about COVID-19 vaccination status among patients with chronic diseases.

included subjects with non specific chronic diseases [14,16-19]. Few studies happened among people with a specific disease. For instance, a study from the USA was to assess the willingness to vaccination among African Americans who recently recovered from COVID-19, even before the actual vaccine was brought into usage [13]. In a study from India by Gaur P et al., they investigated vaccination coverage against COVID-19 among patients with autoimmune rheumatic disease during the early phase of the mass vaccination [15].

Authors estimated the prevalence of COVID-19 vaccine acceptance among patients with chronic respiratory diseases, during the decline phase of the 3rd wave of COVID-19, one year after the beginning of the mass vaccination program against COVID-19. It was found that vaccine acceptance was higher than vaccine hesitancy in subjects with chronic respiratory diseases. However, some subjects were not yet convinced to take vaccine.

A multinational study in the USA, Canada, and other countries, assessed COVID-19 vaccination status among patients with different co-morbidities, including chronic respiratory diseases [18]. The vaccine acceptance ranged from 30% to 81% across these studies [13-19]. In studies that happened before actual vaccination, COVID-19 vaccine acceptance varied from 30% to 52% [13,14,19]. However, in studies that occurred either during the 2nd wave of COVID-19 or after the beginning of the mass vaccination, it spanned from 54% to 81% [15-18].

In the current study, 75% of the participants received at least one dose of a vaccine against COVID-19, whereas vaccine acceptance among patients with chronic respiratory diseases in a multinational study was 82% [18]. This variability was due to multiple factors like country, type of study, population of interest, the time of the

study following vaccine roll out, socio-demographic and cultural backgrounds.

Coming to the causes of vaccine hesitancy or refusal, most of the studies have reported concerns about vaccine safety and associated side-effects [1,3-8]. In a multinational study, self-reported local and systemic reactions were a concern among subjects with chronic respiratory diseases [3]. As COVID-19 is a new disease, some of the participants of these studies have expressed a lack of trust [1,3,7]. As vaccines received emergency approval to control the spread of COVID-19, some of the patients wanted to be watchful about the impact of the vaccine [3,5,6]. Some patients even opined that a vaccine might not be required as it could not boost immunity and prevent reinfection, and natural infection provides better immunity [4]. Some of them had vaccine apathy, as they have not received any other vaccine till now [2,7]. Few patients with chronic diseases felt that following the prevention measures was sufficient to control the pandemic rather than taking vaccines [4,5].

The present study found that intake of native medicine was the most common cause for vaccine refusal among the study population in this region. This was not mentioned in previous studies. Health authorities should address this issue, investigate further and take appropriate measures to drop vaccine hesitancy. Some of the study patients refused to take the vaccine as they had multiple co-morbidities, indicating the low level of knowledge they had about indications for vaccination against COVID-19. Some of the participants, who were afraid of injection, preferred to take vaccine through other routes.

Hypertension, diabetes mellitus, and coronary artery disease were the most common co-morbidities, similar to the present study [1,14,16-18]. Patients with these co-morbidities have a doubled risk of severe COVID-19 [8]. Among chronic respiratory diseases, patients with COPD are at six times greater risk of progressing to severe COVID-19 [8]. COPD was the most common respiratory disease among the present study participants.

Patients with chronic diseases like cardiovascular disease, hypertension, diabetes, cancer, respiratory diseases, and kidney diseases are at enhanced risk of acquiring COVID-19, severe complications, and death due to COVID-19 [2]. The risk of death depends on the number of co-morbidities patients have. It becomes twice in the presence of single co-morbidity and rises to 8 times with five or more diseases [3].

Policymakers need to design multifaceted interventions to reach the goals of vaccination outcomes in specific subgroups at risk [2]. Since there is a lack of sufficient data about vaccine safety in patients with autoimmune diseases, people of this group are in a dilemma about vaccination against COVID-19 [3]. This group of patients was skeptical about the effect of the vaccine on the immune system, like a flare-up of underlying immunological disease [5]. Treating physicians should clarify their doubts about COVID-19 vaccines by providing accurate information. Vaccine hesitancy among subjects with a chronic disease ranged from every alternate patient to one in five, depending on study population [14-20]. However, in the index study every fourth patient with a chronic respiratory disease had vaccine hesitancy. Many people had dilemma about vaccination following COVID-19. Patients who had previous COVID-19 were reluctant to vaccination [3].

The prevalence of vaccine acceptance was equal among the current study subjects with or without previous COVID-19. Uncertainty about vaccine composition with the background of a chronic disease may affect the acceptance of vaccines among these patients [6]. Healthcare providers, like nurses, are expected to have correct information about the vaccines, and they should be ready to educate the patients regarding this. These can fill the gaps in the knowledge of these patients and improve the overall acceptance of vaccines [6]. Patients having family members who developed side effects after receiving a COVID-19 vaccine were likely to refuse it [6].

Vaccination is the only option to control the COVID-19 pandemic lacking specific treatment [7]. To achieve the goals of the vaccination, herd immunity is necessary that hinges on vaccine acceptance by the risk population, 60-75% of the population is to be vaccinated to achieve herd immunity [7]. With increasing the knowledge of patients, improvement in attitudes toward COVID-19 vaccines, and the availability of a safe and effective vaccine at free or minimum cost, wider acceptance of vaccination is possible [7]. Continuous promotion of awareness on the necessity of the COVID-19 vaccine, particularly among patients with chronic diseases, by committed healthcare workers, using different ways of disseminating information, is vital for improving the knowledge and attitude of patients who doubt COVID-19 vaccines [7].

The present study has specific strengths and limitations. It is one of the study that assessed vaccination status among chronic respiratory diseases subjects with higher mean age group. Both are risk factors for severe COVID-19 [7]. Unlike previous studies in India, this study was conducted one year after the launch of mass vaccination and interviewed study participants face to face. Data represent actual numbers at ground level. The study also reports the use of a native medicine in vaccine rejecters.

Limitation(s)

Being a study in a specific population, results can not be generalised. The study did not assess the knowledge of the participants about guidelines of COVID-19 vaccination.

CONCLUSION(S)

One year after starting the mass vaccination in India, vaccine acceptance was more than hesitancy against COVID-19 among subjects with chronic respiratory diseases in South India. Inspite of being a priority community, still some subjects with chronic respiratory diseases have been avoiding vaccine for various reasons. Intake of a native medicine was the most common cause for vaccine hesitancy. This needs further investigation at ground level. Not only framing of central health guidelines and but also providing continuous health education at every possible level to all sectors of the population, imperative to achieve rapid mass vaccination to halt COVID-19 pandemic.

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