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**Original Research Article**

# Clinical profile and outcome of patients with Coronavirus disease 2019 (COVID-19): a large-scale observational study from Tamil Nadu, India

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## ABSTRACT

**Background:** This study aims to assess the socio-demographic and clinical profile of the patients infected with SARS-CoV-2 in Tamil Nadu, India and to identify the associated prognostic determinants.
**Methods:** Facility-level observational data pertaining to the case investigation of 15045 lab confirmed cases of COVID-19 reported in Tamil Nadu from March to June 2020 was used for the purpose of the study. The demographic and clinical profile of the COVID-19 confirmed cases and age-sex specific estimates of severity of illness were analysed. Determinants of prognosis were tested for statistical significance using Chi square and Student t test as appropriate.
**Results:** The mean age was 40±7 years with a male predilection. Thirty six percent of the cases were symptomatic, with fever being the predominant symptom, followed by cough and breathlessness. The Case ICU rate and Case Fatality rate were found to be 6.2% and 2.9% respectively. Increasing age, male sex and underlying comorbid illness were found to significantly affect prognosis in these patients. However, it was observed that females experienced higher risk of severe illness and fatality in the younger age groups.
**Conclusions:** While the observed findings reiterate the prognostic significance of age, gender and comorbidity as evidenced by other studies, the increased risk of severe illness and fatality among younger females provides a new direction for further research from a socio-epidemiological perspective.

**Keywords:** Case fatality rate, Pandemic, Prognosis, SARS-CoV-2

## INTRODUCTION

The COVID-19 pandemic has afflicted 110 million people worldwide with mortality nearing a million deaths.[1] In India, the cumulative cases of COVID-19 have reached 10 million with 1,56,123 succumbing to the infection.[2] Tamil Nadu, a southern state of India is one of the major hotspots of the pandemic in the country with 8.5 lakh cases and 12444 deaths due to the infection.[2]

On 30th January 2020, while the world health organization (WHO) declared the COVID-19 outbreak as a "Public health emergency of international concern"; the first case was reported in India.[3] The first case in Tamil Nadu, however came five weeks later on 7th March 2020. A nationwide lockdown was imposed in the country, soon after the WHO declared COVID-19 as a pandemic on 11th March 2020.[4] Tamil Nadu took pro-active measures to contain the outbreak, while mandating notification of COVID-19 under the Tamil Nadu Public Health Act, 1939.[5]

The National Centre for Disease Control (NCDC), India developed a reporting format termed the case investigation form (CIF), for recording the exposure, clinical illness and outcome of all patients infected with

SARS-CoV2 in the country. The CIF database provides crucial data enabling characterization of the disease and its transmissibility. The present study deals with the analysis of case investigation data of 15,045 COVID-19 positive patients in Tamil Nadu to assess the socio-demographic and clinical profile of the COVID-19 patients and determine the prognostic factors. This could provide crucial insights for controlling the outbreak and mitigating fatalities, by informing systems for triage and subsequent clinical management.

## METHODS

The study presents an analysis of the observational data of COVID-19 patients diagnosed by reverse transcriptase polymerase chain reaction (RT-PCR) method in Tamil Nadu during the period from March to June 2020. The relevant data was obtained from the Case Investigation Form database maintained by the State health informatics division (HID), Tamil Nadu. At the level of the health facility, data pertaining to each case of COVID-19 including socio-demographic, epidemiological, clinical findings and outcome was entered manually in the case investigation form by a healthcare worker. The above data was collected and compiled by the district Rapid Response Team in Microsoft excel; which in turn is collated at the State HID with due consideration for data duplication. Ethical approval was not required for the study since it involves secondary data.

For the purpose of this study, it was decided to use a geographically representative subset from the state CIF database by choosing one district from each of the eight zones earmarked in the State. The data from the eight selected districts was assessed for data quality with respect to completeness of reporting, missing values and outcome updation. Among them, data from two districts were found to have more than 10% missing values for important outcome variables; and in their place, two other districts were randomly chosen which satisfied the data quality criteria.

This resulted in a final sample size of 15045 cases, which were analysed using Microsoft Excel and SPSS version 16. The demographic and clinical profile of the COVID-19 confirmed cases were analysed descriptively. Estimates of severity of illness such as age-sex specific case ICU and case fatality rates were calculated by subgroup analysis. Determinants of prognosis were analysed for statistical significance using Chi square and Student t test as appropriate. Missing values were found to be less than 10% for variables of interest and hence pair wise deletion was followed.

## RESULTS

### *Age and gender distribution*

The mean (±SD) age of the COVID-19 confirmed cases was found to be 40±7 years. Majority were aged between 20 and 40 years (43%) followed by 40 to 60 years (32%) with a minimum and maximum age of 3 days and 95 years respectively. Among the total cases, 63% were males and 37% were females, with 5 cases being reported among transgender persons. As shown in Figure 1, a difference in sex distribution was reflected in all age groups except among those aged less than 20 years, which showed a relatively higher proportion of females (45%) being affected (p<0.001***).

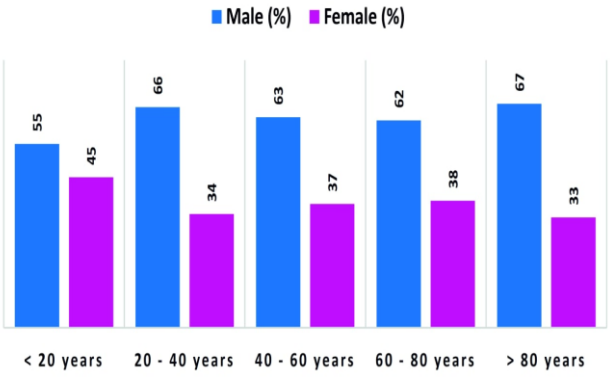


**Figure 1: Gender distribution of COVID-19 cases across age groups, (n=15045).**

### *Clinical profile*

*Symptoms*

Of the 15045 cases, 4740 (36%) were found to have at least one symptom associated with COVID-19 at the time of presentation. Among those who were symptomatic, fever (75%) was the most commonly observed symptom, followed by respiratory symptoms such as cough (50%) and breathlessness (22%). A small proportion (3.7%) presented with gastrointestinal symptoms such as diarrhoea (2.8%) and nausea/vomiting (0.9%).

The mean (±SD) age among the symptomatic cases was observed to be 45±17 years, which was significantly higher compared to 38±16 years among those who were asymptomatic. The observed difference in mean age with 95% CI was 6.7 (6.1, 7.3) years, which was found to be statistically significant (p<0.001***). A significant linear trend was noted with increase in proportion of symptomatic cases from 20% to 61% as the age increases from <20 years to >80 years (p<0.001***). Also, while 38% of affected males were symptomatic, slightly less females (32%) were found to be symptomatic (p<0.001***).

*Comorbidity profile*

The comorbidity profile analysis showed that 18.5% of the study participants had at least one pre-existing comorbidity, with 6% presenting with multiple comorbidities. Diabetes mellitus (11.5%) and hypertension (8.2%) were the most commonly observed

comorbid illnesses among the COVID-19 cases. Other less commonly observed comorbidities include heart diseases (1.9%), respiratory disorders (1.2%), chronic kidney diseases (1.1%), pregnancy (0.7%), neurological disorders (0.3%), malignancy (0.2%), liver disorders (0.2%) and tuberculosis/HIV (0.1%).

While only 11% of those without any known comorbidity exhibited symptoms of COVID-19 infection, thrice the number (33%) of comorbid patients were symptomatic, with the risk of being symptomatic increasing with multiple comorbid illnesses (p<0.001***).

***Severity of illness***

*Case ICU rate (CIR)*

Of the 15045 patients, 795 (6.2%) required admission in an intensive care facility for management of severe illness associated with COVID-19, while a smaller fraction (0.4%) of the cases required respiratory support with mechanical ventilation. Subgroup analysis by age and sex (Table 1, revealed that the risk of ICU admission increased significantly from 2.8% in <20 years to one in four cases (27%) aged more than 80 years (p<0.001***). While the age associated increase in risk is observed in both sexes, an important observation made is that the case ICU rates are higher among males in all age groups except in those <20 years. There is a female predilection in this age group, with 25% increase in risk of severe illness and subsequent ICU admission as compared to males (p=0.77). The case ICU rate is also higher among the comorbid patients (12%) as opposed to those without any comorbidity (4.4%); however, the difference was not statistically significant (p=0.05).

**Table 1: Age and sex categorized case ICU rate in lab confirmed COVID-19 cases, (n=15045).**

| Age group[#] (Years) | General CIR (%) | Male CIR[$] (%) | Female CIR[$] (%) |
|---|---|---|---|
| **<20** | 2.8 | 2.8 | 3.5 |
| **20-40** | 4.1 | 4.6 | 3.5 |
| **40-60** | 6.2 | 6.9 | 5.0 |
| **60-80** | 15 | 17 | 12 |
| **>80** | 27 | 33 | 17 |
| **Overall** | 6.2 | 6.9 | 5.2 |

#Significant at p<0.001*** $Not significant at p=0.77

*Case fatality rate (CFR)*

The observed CFR in this study group was found to be 2.9%, Subgroup analysis by age and sex revealed a similar trend as seen with respect to case ICU rate; with the exception of higher fatality among women extending to the age group of 20-40 years as seen in Table 2. In the subgroup analysis based on severity of illness, as indicated by admission in an intensive care facility, the observed case fatality rates continued to increase with age in both subgroups, but the association with sex was altered. Among ICU admissions, females had higher fatality in the age group of less than 60 years, while males had higher risk of dying in the older age groups. Whereas in patients with mild to moderate illness, seemed to experience higher risk of dying at extremes of age (Table 3).

**Table 2: Age and sex categorized case fatality rate in COVID-19 patients, (n=15045).**

| Age group[#] (Years) | General CFR (%) | Male CFR[$] (%) | Female CFR[$] (%) |
|---|---|---|---|
| **<20** | 0.3 | 0.1 | 0.6 |
| **20-40** | 0.8 | 0.8 | 0.9 |
| **40-60** | 3.4 | 3.8 | 2.9 |
| **60-80** | 12 | 14 | 9.1 |
| **>80** | 22 | 25 | 18 |
| **Overall** | 2.9 | 3.5 | 2.7 |

#Significant at p<0.001*** $Not significant at p=0.95

**Table 3: Interaction of severity of illness on age-sex categorized CFR in COVID-19 patients (n=15045).**

| Age group (Years) | General CFR (%) | Male CFR (%) | Female CFR (%) |
|---|---|---|---|
| **ICU admission (Years), (n=795)** | | | |
| <20 | 7.9 | - | 14 |
| 20-40 | 19 | 16 | 27 |
| 40-60 | 49 | 46 | 58 |
| 60-80 | 72 | 73 | 70 |
| >80 | 78 | 81 | 67 |
| **Non-ICU admission (Years), (n=14250)** | | | |
| <20 | 0.1 | - | 0.2 |
| 20-40 | 0.1 | 0.1 | 0.1 |
| 40-60 | 0.6 | 0.9 | 0.1 |
| 60-80 | 2.7 | 3.3 | 1.9 |
| >80 | 4.2 | 2.3 | 7.1 |

Presence of symptoms of COVID-19 or having an associated comorbid illness was found to be significantly associated with poor prognosis. While a fatal outcome was observed in only 2% of asymptomatic cases, 11% of symptomatic cases succumbed to the infection (p<0.001***). A similar picture was observed with respect to comorbid illnesses, where the CFR was 4% and 11% in non-comorbid and comorbid cases respectively. The comorbidity specific case fatality rates are shown in Table 4. It is seen from Table 4 that patients with malignancy, chronic renal disease and heart disease have the highest case fatality rates with SARS-CoV2 infection. An important finding to be noted is that, while diabetes is the more commonly observed those with hypertension seemed to experience (12.5%) as compared to diabetics mellitus (10.3%).

When comparing prognostic outcomes among comorbid and non-comorbid patients, it was noted that all outcomes of poor prognosis including developing symptoms with

COVID-19 (62% vs 28%; p<0.001***), admission in an intensive care unit (9.1% vs 1.6%; p=0.018*) and death (11% vs 4%; p=0.06) were more frequent among comorbid as compared to non-comorbid persons (Figure 2).

**Table 4: Comorbidity specific CFR in COVID-19 confirmed cases.**

| Comorbidity | Number of cases | CFR (%) | 95% CI |
|---|---|---|---|
| **Malignancy** | 27 | 26 | 9.5, 42.5 |
| **Chronic renal disease** | 149 | 22 | 15, 29 |
| **Heart disease** | 242 | 16.5 | 12, 21 |
| **Chronic neurological disorders** | 38 | 13.2 | 2.4, 24 |
| **Hypertension** | 1056 | 12.5 | 10.5, 14.5 |
| **Tuberculosis** | 19 | 10.5 | -3.3, 24 |
| **Diabetes mellitus** | 1377 | 10.3 | 8.7, 12 |
| **Respiratory disorders** | 154 | 9.1 | 4.6, 14 |
| **Pregnancy-related** | 70 | 1.4 | -1.4, 4.2 |

***Length of hospital stay***

The median length of hospital stay was 9 (6-10) days in these patients, as per the discharge policy adopted. Hospital stay also seemed to play a role in predicting prognosis, as most deaths of COVID-19 occurred within the first 3 days. A significant difference was seen in the median (IQR) hospital stay between those who died and recovered from COVID-19, which was 3 (1-6) days and 9 (7-10) days respectively.

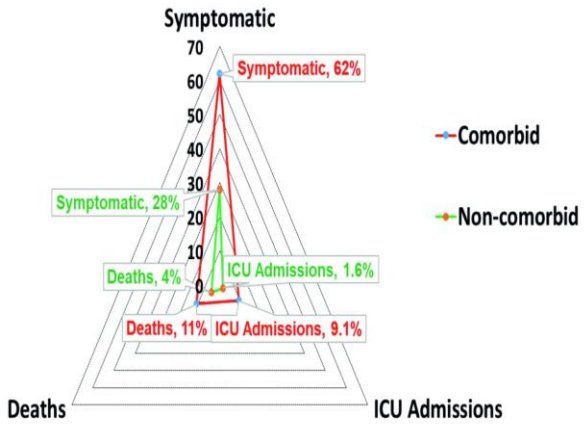


**Figure 2: Prognostic comparison of COVID-19 patients with and without comorbid illness, (n=15045).**

## DISCUSSION

The peak age of COVID-19 patients in this study falls between 20 and 40 years, which is in consonance with recent evidence stating that younger people are the major drivers of the pandemic.[6] The observed male preponderance may be due to different rates of exposure associated with gendered nature of occupation and social participation.[7-9] However, among those aged less than 20 years, the comparable proportion of cases among both sexes may be attributed to the lockdown and associated movement restriction.

COVID-19 is a systemic illness and the symptoms are varied-the disease presentation can range from being asymptomatic to severe respiratory distress and death.[10]As evidenced by studies elsewhere, manifestation of COVID-19 symptoms was more commonly observed with advancing age and among males.[11-13] Social and behavioural factors such as smoking which are associated with poor prognosis, may be related to the poor outcomes among males.[14] Many studies have already established the high prevalence of hypertension, diabetes and cardio-vascular disease in COVID-19 patients.[11,13,15] The present study also affirms that persons with multiple-co morbidities are more likely to exhibit symptoms as compared to those without comorbidities.[16,17]

The case ICU rate in the current study was found to be 6.2%, while 0.4% required mechanical ventilation. The elderly, males and comorbid patients especially those with multiple comorbidities were found to have higher rates of ICU admission in this study. Systematic reviews and meta-analyses done elsewhere corroborate the above findings, highlighting the role of diabetes, hypertension and COPD in severe prognosis.[18-20] However female predilection to severe disease in the younger age group (<20 years) is a new finding in this study, that needs exploration into plausible biological and socio-economic determinants.

When comparing extremes of age, risk of death increases by approximately 73 times as age category shifts from less than 20 years (0.3%) to greater than 80 years (22%). Overall, males with a CFR of 3.5% were observed to have a 30% higher risk of dying compared to females (2.7%) in the present study. However, the female CFR was found to be higher than males in cases under 40 years of age, which needs further evaluation. It was evidenced by multiple studies that CFR was strongly associated with factors such as increasing age, being male, and pre-existing co morbidities such as diabetes, hypertension, cancer etc.[11,13,21]A large systematic review and meta-analysis has also evidenced that male gender and age greater than 50 years were independent predictors of mortality among COVID 19 patients admitted in ICU.[22]

The study established that symptomaticity, CIR and CFR were higher among comorbid patients as compared to non-comorbid. These findings are in keeping with current knowledge that those with comorbidities are more liable to poor prognosis.[11,15] The prime focus of the health system should be to screen, detect, confirm, triage, manage, follow-up and to avoid preventable deaths. The

identification of the major comorbid risk factors and taking appropriate clinical measures during the golden period can contribute in saving many lives.

In this study, malignancy was associated with the highest CFR of 26%, substantiated by studies elsewhere.[23,24]A study in New York hospital system found that CFR in patients with cancer was 37% for patients with haematological malignancies and 25% for solid malignancies.[25] However, diabetes and hypertension being widely prevalent in Tamil Nadu, they are most commonly associated with COVID-19 deaths in the state.[26] Diabetes as a major risk factor for rapid progression and poor prognosis of COVID-19 is established universally.[27] Bloomgarden et al stated that CFR from pneumonia among patients with diabetes in Hong Kong (age≥75) exceed mortality rates in this age group from cardiovascular disease and cancer.[28] The possible pathophysiological mechanisms of the relationship between each of these comorbidities (diabetes, hypertension, CHD, CKD, Cancer etc.) and COVID-19, post-COVID 19 sequelae and its management needs to be widely studied and further research in this regard is required for better clinical management of both.

The median (IQR) hospital stay was 9 (6-10) days, which could be attributed to the discharge protocol followed in the country, which allows discharge after 10 days of symptom onset, provided the patient is symptom free for 3 days prior.[29]Atleast 50% of the deaths occurred within the first 3 days of hospital stay. The study by Wang et al also establishes the shorter length of stay among the dead: 5 (3-8) vs. 28 (26-29) days among those who recovered.[30] Analysis of length of hospital stay is crucial for planning and allocation of health resources and designing effective patient management protocols to circumvent time delays.

## CONCLUSION

The observed findings suggest that age, gender and comorbidity play a significant role in the prognosis of COVID-19 patients. In particular, the increased risk for severe outcomes among younger females has to be further explored in-depth through a gender-based framework. In the current context of an aging population and rising burden of NCDs, the combination of NCDs and COVID-19 may pose a huge challenge to the clinical management of both. The study findings have implications for risk stratification, standardized clinical management and targeted interventions for the vulnerable population for effective mitigation of the pandemic.

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*Conflict of interest: Authors are currently working in Department of Health and Family Welfare, Government of Tamil Nadu.*
*Ethical approval: The study was done using secondary data analysis of the CIF data, though administrative approval was obtained from Directorate of Public Health & Preventive Medicine, Tamil Nadu*

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