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Original Research Article

COVID-19 disease and comorbidity: an outcome? A study on Indian population in a COVID care hospital

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ABSTRACT

Background: The world has been severely affected by the novel coronavirus disease (Covid-19). Continuously rising number of cases has put a significant strain on healthcare resources of all countries of the world. Preliminary studies show that people suffering from comorbid conditions are at a relatively higher risk of severe disease and poor outcome.
Methods: We studied the risk of ICU admission in 152 Covid-19 positive patients with comorbidity compared to those without comorbid conditions. We studied effect of old age (>65 years), male sex, presence of at least one comorbidity, presence of multiple comorbidities, diabetes mellitus, hypertension, CAD, respiratory disease, neurological disease, skin disease, and hypothyroidism on outcome of coronavirus disease with two tailed Student's t-test, odds ratio, Chi-square test was used to test significance of results at 95% confidence interval 95% (95% CI). Fisher's test was also used if one expected value (row total × column total/grand total) was less than 5.
Results: In this study, 23 (15.13%) required ICU care. We found higher odds of ICU admission in Covid-19 patients in case of presence of comorbid condition (OR=7.3, 95% CI=2.674, 20.038), diabetes mellitus (OR=2.8, 95% CI=1.035, 8.028), hypertension (OR=1.3, 95% CI=0.396, 4.258), coronary artery disease (OR=2.3, 95% CI=0.430, 12.978) and malignancy (OR=6.5, 95% CI=1.516, 28.54). Case fatality rate (CFR) of those with comorbid conditions was higher (7.55) compared to those without comorbidity (3.03).
Conclusions: This study shows that presence of comorbid conditions in Covid-19 positive patients results in significantly higher risk of ICU admission and poor outcome.

Keywords: Comorbidity, Critical care, Death, Outcome

INTRODUCTION

The world has come under the grip of an infectious disease, caused by novel coronavirus named as Covid-19 and has been declared pandemic by World Health Organisation.[1] It is highly contagious disease.[2] The clinical spectrum of Covid-19 ranges from asymptomatic disease to severe respiratory illness causing acute respiratory distress syndrome (ARDS), pneumonia and death.[3]

Respiratory compromise and decrease oxygen saturation leads to death in critical Covid-19 positive patients.[4]

Preliminary studies have shown incidence of severe disease in 12.6 to 23.5 percent people affected with Covid-19.[3,5] This finding, coupled with highly contagious nature of Covid-19, has resulted in significant strain on intensive healthcare units across the world.[6,7]

Few reports have shown that men, elderly, those having comorbid conditions such as diabetes mellitus, hypertension, coronary artery disease (CAD) and chronic respiratory disease are at an increased risk of severe disease, poor disease outcome and higher mortality.[3,5-18]

We aimed to assess, if presence of comorbid condition is associated with outcome of Covid-19 compared to those without comorbidity.

METHODS

Study design and data collection

The present study was an observational study performed on patients presenting at Rajiv Gandhi Super Speciality hospital, tertiary care hospital for a period of August to October, 2020. Our study sample consisted of Covid-19 cases and grouped them into positive and negative, indeterminate cases. Further we divided them into two categories, those with comorbidities and those without comorbidities. The data was extracted from patient medical records and compiled into worksheet by experienced clinicians. The endpoint was defined as ICU admission or death, and patients under each category were further classified into those who required ICU care and those who did not (non-ICU care), as shown in Figure 1.

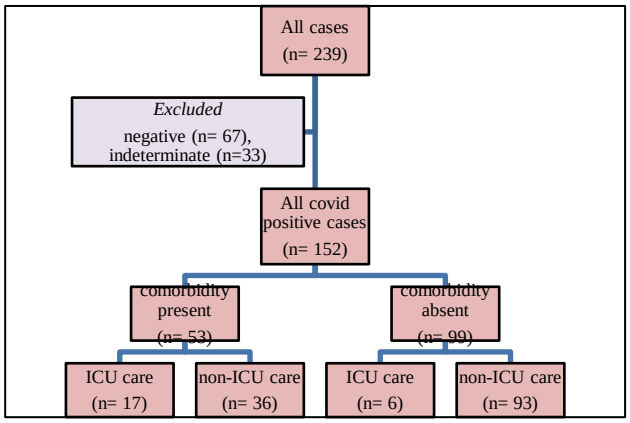

Figure 1: Sample size of study (n=152) after exclusion of cases, which did not meet the inclusion criteria.
The distribution tree shows distribution of Covid-19 positive cases with comorbidity and without comorbidity; and number of patients with ICU admission under each group.

Inclusion criteria

Only those with positive test results (n=152) for Covid-19 by nucleic acid amplification and detection using real time RT-PCR were included in the study.

Exclusion criteria

Those with negative (n=60) and indeterminate test results (n=27) were excluded.

The comorbid conditions studied in the population were listed. These included type 2 diabetes mellitus, hypertension, coronary artery disease (CAD), respiratory disease (including COPD, asthma, tuberculosis, and interstitial lung disease), malignancy, neurological disease, hypothyroidism and skin disorders. Multiple comorbidities were defined as chronic conditions involving two or more different organ systems. Patient clinical data about presence of only these comorbidities was extracted for our study purpose.

Patients were admitted to ICU as per ICMR (Indian Council of Medical Research) guidelines.[16] Those with signs and symptoms indicating severe disease: fever or suspected respiratory infection with either tachypnea (respiratory rate >30 per minute), peripheral capillary oxygen saturation <90% on room air, clinical or radiological signs of acute respiratory distress syndrome; and respiratory failure, septic shock or multi-organ failure, were admitted to ICU. All Covid-19 positive patients received treatment as per the recommended protocols of ICMR for severe and non-severe disease (all Covid-19 positive patients who died during the course of their illness were also included to assess mortality. All such patients required ICU care before death).[16]

Those with symptoms and signs of mild disease including fever (temperature more than 38.0 degree centigrade), mild tachypnea and no pneumonia; and moderate disease including mild pneumonia. Such patients were admitted to ward.

Statistical analysis

Statistical analyses were conducted using IBM SPSS Statistics software (Chicago, IL, USA). Continuous variables were represented as mean and standard deviations, while categorical variables were presented as counts and percentages. Our null hypothesis was that there is no difference in proportion of Covid-19 positive patients admitted to ICU with or without risk factors (age >65 years, male sex, presence of at least one comorbidity, presence of multiple comorbidities, diabetes mellitus, hypertension, CAD, respiratory disease, neurological disease, skin disease, and hypothyroidism) compared non-ICU care group.

Two tailed Student's t-test was used to test the significance of continuous variables (age), with probability of type-I error (alpha) kept at <0.05 (95% confidence interval), in the above stated two groups. Odds ratio (OR) was calculated to assess correlation of categorical variables. Cross-tabulation and Chi-square test was used to test significance of results at 95% confidence interval 95% (95% CI). Chi-square value was derived from calculation of expected frequencies. Level of significance was 0.025 on either side of the curve (2-sided p). If one expected value (row total×column total/grand total) was less than 5, then Fisher's exact test was used.

RESULTS

Medical records data of a total of 252 patients was collected. Of these, 67 Covid-19 negative patients and 33 patients with inconclusive test results were excluded and

Covid-19 positive patients (n=152) were studied further. Among these, 53 (34.8%) patients presented with comorbid conditions (listed previously) while 99 (65.2%) had no comorbid conditions. In our study, 23 (15.13%) required ICU care. Of those with comorbidities, 17 (32.1%) required ICU care while, only 6 (6.1%) of those without comorbidities required ICU care (Figure 1).

Table 1: Mean age of study population, patients in ICU care and non-ICU care group and those who died and those who survived.

	No. of cases	Mean age±SD	P value	95%CI
All cases	152	48.8±17.3	-	-
ICU care	23	49.26±17.843	0.884	-7.170, 8.312
No ICU care	129	48.69±17.215		
Died	7	48.71±17.036	0.992	-13.301, 13.171
Survived	145	48.78±17.321		

Two- tailed Student's t-test was used to test for significance of difference of means in the two age groups with 95% confidence interval (95% CI).

The mean age of our study population (n=152) was 48.8 years (SD 17.3, range 9 to 95 years). Our study population consisted of 121 (79.6%) men and 31 (20.4%) women. Men were affected about 3.9 times the number of women (Table 1).

Age and disease outcome

Table 1 also shows that there was no statistically significant difference in mean age of Covid-19 positive patients requiring ICU care (49.2 years, SD 17.8) compared to those who did not (mean 48.7 years, SD 17.2) with p value 0.884, 95% CI (-7.170, 8.312). Patients with old age (>65 years) also did not show higher odds of ICU admission [OR=0.796, 95% CI (0.2163, 2.426)] compared to younger patients. Statistical analysis shows that there was no significant mean age difference in Covid-19 positive patients who died (n=7, mean 48.7 years, SD 17.0) compared to those who survived (mean 48.8 years, SD 17.3) with p value 0.992, 95% CI (-13.3, 13.2). The age distribution in Figure 2 shows maximum number of Covid-19 positive cases requiring ICU care fall in age group 21-30 years and 51-70 years.

Sex and disease outcome

In our study, 17 (14.0%) men and 6 women (19.3%) required ICU care as seen in Table 2. Statistical analysis did not reveal any significantly higher odds of ICU admission [OR=0.681, 95% CI (0.244, 1.904)] compared to women. Out of 7 patients who died, 6 were men and one woman. Male sex did not result in statistically significant death rate in comparison to their female counterpart [OR= 1.56, 95% CI (0.2194, 37.4)].

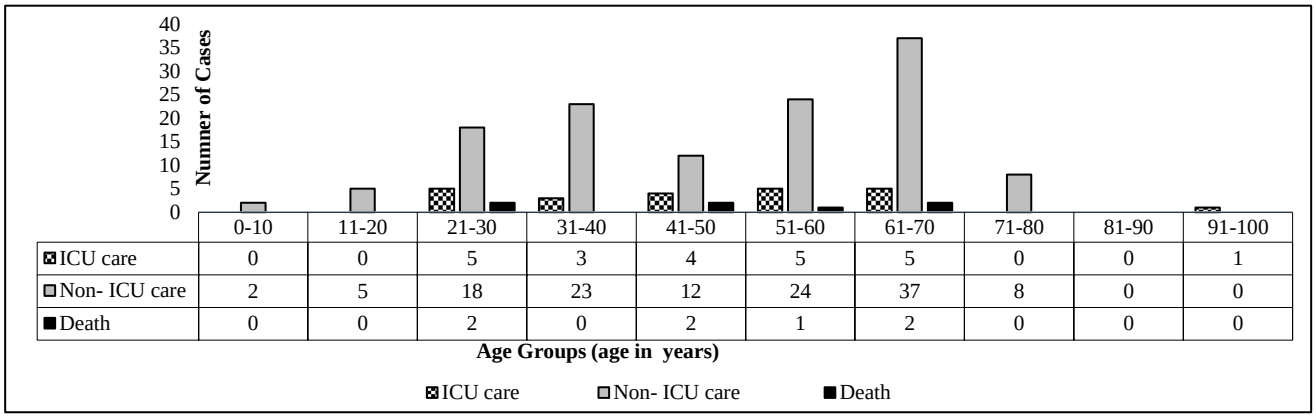

Figure 2: Age distribution of Covid-19 positive cases requiring ICU care and non-ICU care.

Bar chart shows age distribution of Covid-19 positive cases which required ICU care (texture fill) and those which did not require ICU care (grey colour). The deaths in each age group due to Covid-19 are also depicted (solid black colour).

Comorbidity and disease outcome

At least one comorbidity was present in 53 (34.8%) patients in the sample. Of these, 24 (15.8%) patients had diabetes mellitus, 22 (14.5%) had hypertension, 8 (5.3%) had respiratory disease, 7 (4.6%) had CAD, 8 (5.3%) had malignancy, 2 (1.3%) had neurological disease, 4 (2.6%) had hypothyroidism and 2 (1.3%) had skin disease. There were 21 (13.1%) patients who had multiple comorbidities (Table 2).

A total of 23 (15.1%) patients required ICU care. This was seen in 17 (32.1%) patients with at least one comorbidity and only 6 (6.1%) patients with no comorbidity, with high odds ratio [OR=7.32, 95% CI (2.674, 20.038)] suggestive of higher odds of ICU care in those with comorbidity (Table 2). It is also evident that, patients with either diabetes mellitus [n=24, OR=2.88, 95% CI (1.035, 8.028)] or malignancy [n=8, OR=6.58, 95% CI (1.516, 28.54)] had significantly higher odds of requiring ICU care, than those without either of these

comorbidities. However, Covid-19 positive patients with either hypertension [n=22, OR=1.29, 95% CI (0.396, 4.258)], CAD [n=7, OR=2.36, 95% CI (0.430, 12.978)] or hypothyroidism [n=4, OR=1.91, 95% CI (0.190, 19.195)] did have a higher odds of ICU admission, however, it was not statistically significant, compared to patients with no such comorbidities. Those with respiratory disease did not show any correlation with ICU admission [n=8, OR=0.79, 95% CI (0.093, 6.760)]. Data was inadequate for neurological disease (n=2) and skin disease (n=4). Importantly, 5 (23.8%) of Covid-19 positive patients with multiple comorbidities required ICU admission, while 23 (17.5%) with none or one comorbidity required ICU care. Thus, patients with two or more comorbidities did have a comparatively higher ICU admission rate compared to those with one or no comorbidity. However, the odds ratio was not statistically significant [OR=1.96, 95% CI (0.640, 6.016)] (Table 2).

Table 2: Distribution of Covid-19 positive cases requiring ICU care and non-ICU care, and odds of ICU admission in patients with various risk factors.

Demographic or comorbid risk factor	Total no. of cases	ICU admission	No ICU admission	Odds ratio	95 % CI	Chi-square value	P value	No. of patients died	CFR (% for all cases)
Age ≥65 years	31	4 (12.9%)	27 (87.1%)	0.7965	0.2163, 2.426	0.1506	0.6980	1	3.22
Male sex	121	17 (14.0%)	104 (85.9%)	0.681	0.244, 1.904	0.541	0.462	6	4.96
Comorbidity present	53	17 (32.1%)	36 (67.9%)	7.319	2.674, 20.038	18.192	0.00001997	4	7.55
Diabetes mellitus	24	7 (29.2%)	17 (70.8%)	2.882	1.035, 8.028	4.372	0.037	2	8.33
Hypertension	22	4 (18.2%)	18 (81.8%)	1.298	0.396, 4.258	0.186	0.666	1	4.55
Respiratory disease	8	1 (12.5%)	7 (87.5%)	0.792	0.093, 6.760	0.046	0.831	1	12.5
CAD	7	2 (28.6%)	5 (71.4%)	2.362	0.430, 12.978	1.032	0.310	0	0
Malignancy	8	4 (50%)	4 (50%)	6.579	1.516, 28.54	7.995	0.005	2	25
Neurological disorder	2	2 (100%)	0 (0%)	-	-	-	-	1	50
Hypothyroidisn	4	1 (25%)	3 (75%)	1.909	0.190, 19.195	0.312	0.577	0	0
Skin disease	2	2 (100%)	0 (0%)	-	-	-	-	0	0
Multiple comorbidities (compared to one or none)	21	5 (23.8%)	16 (76.1%)	1.962	0.640, 6.016	1.429	0.232	2	9.52
Total (overall)	152	23 (15.13%)	129 (84.9%)	-	-	-	-	7	4.60

The odds ratio (OR) was calculated using Chi-square test with 95% confidence interval to assess correlation with demographic variables and comorbid conditions with risk of ICU admission.

Table 3: Distribution of patient who died, who survived and odds for mortality in Covid-19 positive cases with various risk factors.

Demographic and comorbid risk factors	Patients died	Patients survived	Total cases	Odds ratio	95 % CI	Chi-square value	P value
Age >65 years	1	30	31	0.6405	0.02674, 4.558	0.1687	0.6813
Male sex	6	125	121	1.561	0.2194, 37.4	0.1687	0.7591
Comorbidity present	4	49	53	2.594	0.5169, 14.39	1.603	0.2432

The odds ratio (OR) was calculated using Chi-square test with 95% confidence interval to assess mortality risk in Covid-19 positive patients with demographic and comorbid risk factors

Mortality

Amongst those who died (n=7), one had age >65 years, and 6 had age <65 years. Overall the case fatality rate (CFR) of Covid-19 patients was 4.6 percent. CFR for those with comorbidity was higher at 7.55 compared to those without comorbidity (3.03) (Table 2). Presence of comorbidity in Covid-19 patients showed higher odds of mortality compared those without comorbidity, however, the results were not statistically significant [OR=2.594, 95% CI (0.5169, 14.39)]. CFR for Covid-19 patients with individual comorbid conditions was also higher, with diabetes mellitus as 8.33, hypertension as 4.55, respiratory disease as 12.5, malignancy as 25.0; in comparison to non-comorbid patients. Rigorous statistical analysis using chi-square and Mid-P exact tests did not yield higher odds of mortality for age >65 years [OR=0.640, 95% CI (0.02674, 4.558)] or male sex [OR=1.561, 95% CI (0.2194, 37.4)] (Table 3).

DISCUSSION

Ours is the first investigation report from a Covid-19 dedicated hospital that systematically evaluates the impact of comorbid conditions on outcome of Covid-19 positive patients in Indian population. Our study results show that diabetes mellitus, hypertension and CAD were the most common comorbidities observed in Covid-19 patients, which is also reflected in recently published studies.[8] The proportion of people having severe Covid-19 disesase necessitating ICU care was 15.3%, similar to erstwhile published studies (12.6 to 23.5%).[5]

Our study results echo previous studies, with cases of Covid-19 seen in all age groups and the mean age of affected individuals being 48.8 years.[8] A man to woman ratio of almost 4:1 in Covid-19 positive cases suggests higher prevalence in men compared to women. Increased men to women ratio of Covid-19 positive cases has also been noted in a study by Nikpouraghdam et al.[15] However, compared to previously published reports, advanced age (≥65 years) or male gender did not yield statistically significant odds of poor outcome in Covid-19 positive patients in our study.[12-14] The underlying reason for this observation compared to other published studies, needs to be investigated.

Our study proves that the presence of even one chronic comorbid condition results in significantly increased risk (seven-fold) of poor outcome in Covid-19 patients. Similar results have been obtained in studies from China.[5,8,9,12-14] Our study stands out as the first study of Covid-19 positive patients of Indian population which systematically validates the observation of increased risk of poor outcome in patients with comorbid conditions.

The underlying patho-physiological mechanisms may provide an insight into increased risk of poor outcome in patients with comorbidity and help develop novel therapeutic ways to treat them. One of the postulated mechanisms states that the patients with chronic diseases are predisposed to severe illness due to weakened immune system.[17] A study by Ye et al, states that Covid-19 causes “excessive and prolonged cytokine/chemokine responses” resulting in “cytokine storm”, which leads to ARDS and multiple organ dysfunction.[18] A study by Liu et al, demonstrated reduced peripheral CD_3+ CD_8+ cell count in Covid-19 positive patients, suggesting reduced cell medicated immunity in such patients.[19] Exaggerated cytokine response and reduced immunity coupled with various degrees of organ dysfunction leading to significant functional impairment, may help explain the underlying immuno-patho-physiological process leading to adverse disease outcome in Covid-19 patients with comorbidity. This assertion needs to be investigated for development of drug therapy.

Our results also state that patients two or more comorbid conditions simultaneously are at least two-fold increased risk of adverse disease outcome compared to those with one or no comorbid condition. A study by Zhou et al, has similarly, shown increased odds of mortality in patients with higher sequential organ failure assessment (SOFA) score.[10]

We recommend appropriate detailing of past medical history of Covid-19 cases, to triage them into those with comorbid conditions and those without such conditions. We also recommend prioritization of intensive care unit beds and early initiation of supportive therapy for patients with comorbidity, who are at increased risk of poor outcome. We also recommend prioritization of those with multiple comorbidities over those with one comorbidity for admission to ICU.

Individually, diabetes mellitus was associated with three-fold, coronary artery disease almost 2.5 times, hypertension 1.2 times, malignancy seven-fold and hypothyroidism two-fold risk of of poor disease outcome. However, only diabetes mellitus and malignancy showed strong correlation, while strength of correlation of Coronary artery disease and hypertension was not statistically powerful. Our study results are consistent with and corroborate those published previously in literature.[5,8,9,12-14] However, in comparison to these studies, our study results did not yeild significantly higher risk in patient with respiratory disease. This may be due to early initiation of supportive treatment in such patients, given the involvement of respiratory system by SARS-CoV-2. The early intervention or small sample size may have confounded the results, which needs to be investigated. No cases of chronic liver and renal diseaseas were encountered in Covid-19 positive patients. This observation is consistent with a metanalysis report by Wang et al.[9]

Based on these observations, we also recommend a graded scoring wherein, risk of poor outcome associated with specific comorbid conditions can be calculated. This

will help guide decision making for prioritization of admission to intensive care units.

Covid-19 is the third epidemic caused by coronavirus. The case fatality rate of Covid-19 infection in our study was 4.6%. This is similar to a study done by Sun et al (4.3%) among others.[3] The previous two epidemics, SARS in 2002 and Middle East respiratory syndrome (MERS) in 2012, had very high mortatlity rates of 11.0% and 29.8% respectively, and were contained.[20,21] SARS and MERS led to death of 774 and 885 people worldwide.[22,23] The present Covid-19 epidemic, though, has lower mortality rate, but being highly contagious has killed more than three hundred thousand people worldwide. Despite comparatively low case fatality ratio, precaution must be exercised through improved sanitation and better personal hygeine to prevent the spread of SARS-CoV-2.

CFR for Covid-19 positive with comorbidity was comparatively higher at 7.55 compared to those without comorbidity (3.03) demonstrating two-fold increased risk of mortality in such patients and corroborates with previous studies.[5,11,13] Patients with diabetes mellitus, hypertension, respiratory disease and malignancy had higher CFR compared to non-comorbid patients. This is consistent other published studies which show higher odds of death with these risk factors.[10,11,13-15] However, due to small number of people in our study who died, pooled retrospective analysis of such patients is required to assess mortality risk.

Our study had a few limitations. The size of study population and of individual comorbid conditions was relatively small for an epidemiological study. To compensate this limitation, we used more conservative and rigorous statistical tools to test the significance of our results. Our analysis is based on data obtained from a single Covid-19 dedicated tertiary care hospital. An ideal epidemiological study warrants, pooled data from multiple centres to reduce heterogeneity of population. However, this was not possible for want of time. Our study sample was subjected to selection bias, as only proven were included in the study and it may not be truly representative of population. However, the proportion of comorbidities noted in our study is similar to that seen in general population. We are well informed of limitations of the present study, however, the urgency of situation to provide objective estimates about the ongoing pandemic necessitated accommodation of these limitations.

CONCLUSION

The Covid-19 pandemic is going on with increasing number of deaths per day. In the absence of proven vaccine or efficacious medical treatment, we recommend appropriate detailing of past medical history, triaging patients based on presence or absence of comorbidity and number of such comorbid conditions, and then prioritizing those with highest risk for early intensive care and supportive therapy. We also recommend prospective study using large multi-centric pooled data of various demographic, clinical, laboratory and other risk factors from various parts of the country for assessment of poor outcome of patients in the current pandemic.

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