Original Research Article

COVID-19 vaccination status and treatment outcome: An observational study in a dedicated COVID Hospital of North East India

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ABSTRACT

Background: Vaccination has been recommended to curve the COVID-19 pandemic. Associations of death among COVID-19 patients with their COVID-19 vaccination status and various co-morbidities are ill understood.

Objectives: To compare the proportions of death between COVID-19 vaccinated and un-vaccinated and to determine the association of vaccination status and selected co-morbidities with death among COVID-19 patients treated in the DCH of Tripura.

Materials and Methods: This secondary data based cross-sectional study was conducted in the DCH of Agartala Government Medical College using medical records of 2354 COVID-19 patients treated during second and third quarters of 2021, chosen by simple random sampling. A pre-designed proforma was used to extract data regarding demographics, vaccination status, co-morbidities, vitals, treatment outcome etc. from the case-sheets. Binary regression model was utilized for predicting the probability of death due to COVID-19 using important predictor variables.

Result: Majority i.e. 68% patients were aged between 18 to ≤60 yr, 56.7% were male, 38.3% had co-morbidities, 11% received single dose, 9.6% received two doses and 79.4% had no COVID-19 vaccination. Death rate was 5.8% among first dose recipients, 9.3% among second dose recipients and 11.4% among un-vaccinated. Overall death rate was 7.4%. Binary regression model has shown that older age, poor oxygen saturation during hospitalization, chronic kidney disease, hypertension and diabetes mellitus are having significant enhancing effect and vaccination having protective effect upon death.

Conclusion: Old age, diabetes mellitus, hypertension and chronic kidney disease have enhancing and vaccination has got protective effect against death due to COVID-19.

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1. Introduction

Corona Virus Disease 2019 (COVID-19) attracted worldwide attention by causing international public health emergency in the form of pandemic. Globally there have been 38,35,09,779 confirmed cases of COVID-19 including 56,93,824 deaths reported to WHO till 3rd February 2022 and total 10,04,07,66,359 vaccine doses have been administered till 1st February 2022.[1] In India COVID-19 vaccination was started since 16 Jan 2021 and most healthcare and frontline workers were vaccinated with COVISHIELD[δ] (manufactured by Serum Institute of India Pvt Ltd, Pune, India). The process of vaccinating the elderly

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(>65yrs) and those above 45 years with co-morbidities was undertaken thereafter. A total of 1,58,17,96,355 COVID-19 vaccine doses have been administered in India till last week of January 2022.[1]

As of now, Tripura, a north-eastern state of India reported administration of 26,29,840 nos 1st doses and 21,74,459 nos 2nd doses of COVID-19 vaccine, 1,00,584 confirmed cases and 915 deaths due to COVID-19.[2] Apart from social distancing, vaccines to prevent SARS-CoV-2 infection are considered as the most promising approach for curbing the pandemic. By the end of 2020, several vaccines had become available for use in different parts of the world, over 40 candidate vaccines were in human trials, and over 150 were in preclinical trials.[3]

Immunity against SARS-CoV-2 virus causing COVID-19, achieved after infection, was shown to be variable in its duration and efficacy.[4] Regardless of efficacy, prioritized vaccination of >60 years has led to greater reduction in deaths than prioritized vaccination of other age groups.[5] Different studies on COVID-19 suggest that a range of 60% - 75% immunization of the total population would be necessary to control the spread of SARS-CoV-2.[6] Miscellaneous COVID-19 mortality rates have been reported as determining an accurate mortality rate is still a challenge and might not be achievable. Studies had shown various factors to be associated with mortality in COVID-19.[7] Mortality rates show an increase in older populations having underlying diseases.[8] Diabetes mellitus, cardiovascular disease, chronic kidney disease, chronic pulmonary disease etc. were found to be present in large number of COVID-19 patients.[9]

Few previous studies showed that DM and CVD as underlying co-morbidities might increase the risk of death in patients with COVID-19,[10] but, they have failed to provide robust evidence on these associations because of too small sample size, which led to the low precision of the estimations, and lack of taking confounding factors into consideration.[11]

Presentations, co-morbidities, vaccination status and their associations with death due to COVID-19 may vary across different socio-demographic, and ethno-cultural and geographic areas. Population of Tripura differ from rest of the nation regarding all these factors. Understanding these issues may help to provide adequate and in-time personalized care based up on individual's conditions. Hence the present study has been designed to generate evidence based modelling of COVID-19 by addressing variables that might be related to an alteration in the mortality rates of in patients of DCH of a north-eastern state.

2. Materials and Methods

This secondary data based cross-sectional study was conducted in the DCH of Agartala Government Medical College using medical records of 2354 COVID-19 patients treated between 1st April 2021 to 30th September 2021. Minimum sample size requirement for this study was determined using the formula[12] for calculating sample size in prevalence studies using proportion, considering the death rate of COVID-19 patients treated in DCH as 13.72%[13] at 95% confidence with 10% relative error. It was calculated to be 2417. A sampling frame was prepared using MRD number of all the patients admitted in the DCH during the study period. Simple random sampling without replacement was followed to choose the desired number of case-sheets. Among them 17 case-sheets had missing data, 11 had medico legal issues, 19 cases were referred outside for management and 16 left the DCH against medical advice before treatment completion. Thus 63 cases were excluded and final sample size came down to 2354, which were included in analysis.

Only the records of COVID-19 cases diagnosed either by RAT or RTPCR were included in this study. Treatment outcome was dichotomised in the form of either 'recovered' or 'died'. Deaths occurring among the COVID-19 patients while under treatment in the DCH irrespective of duration of treatment were considered as death due to COVID-19. Those once discharged in recovered status were considered as recovered.

A pre-designed proforma was used to extract data regarding demographics, vaccination status, co-morbidities, vitals, treatment outcome etc. from the case-sheets. Later on these were entered in computer and analysed using Statistical Package for Social Sciences-25 for windows.[14] Mean and SD were used to summarise the continuous variables. Chi-square test was performed to test the significance of difference between different proportions. Binary logistic regression model was utilized for predicting the probability of death due to COVID-19 using selected predictor variables. P-values less than 0.05 were considered statistically significant. Data were handled with strict confidentiality. Institutional Ethics Committee of Agartala Government Medical College has approved this study vide letter no. F.4(5-234)/AGMC/Academic/IEC Meeting/2020/12253.

3. Result

Among 2354 COVID-19 patients treated in the DCH between 1st April 2021 to 30th September, 1603 (68%) were aged between 18 to <60 yr, 636 (27%) were aged either 60 yr or more and 118 (5%) were aged less than 18yr. Among them, 1337 (56.7%) were male, 2242 (95.1%) were Hindu by religion, 1442 (61.2%) were from West Tripura district where the DCH was located, 902 (38.3%) patients had some form of co-morbidities, 259 (11%) patients were vaccinated with the first dose of COVID-19 vaccine, 226 (9.6%) received two doses of the vaccine and 1872 (79.4%) were not vaccinated at all.

Table 1: Treatment outcome by vaccination status of the study subjects.

Variables	Subgroup	Treatment outcome		Significance
		Cured Number (%)	Died Number (%)	
Vaccine doses received	One dose	244 (94.2)	15 (5.8)	
	Two doses	205 (90.7)	21 (9.3)	χ^2= 7.944 p = 0.019
	Not received	1659 (88.6)	213 (11.4)	
Vaccination status	Partial & full	449 (92.6)	36 (7.4)	χ^2= 6.379 p = 0.012
	Unvaccinated	1659 (88.6)	213 (11.4)	

Table 2: Treatment outcome by co-morbid conditions of the study subjects.

Variables	Subgroup	Treatment outcome		Significance
		Cured Number (%)	Died Number (%)	
Co-morbidity	Present	792 (87.8)	110 (12.2)	χ^2= 4.113 p = 0.043
	Absent	1316 (90.4)	139 (9.6)	
Glycaemic status	Diabetic	325 (87.8)	45 (12.2)	
	Non-diabetic co-morbidities	457 (87.5)	65 (12.5)	χ^2= 0.994 p = 0.3188
	No co-morbidity	1329 (90.72)	136 (9.28)	
Blood pressure	Hypertensive	594 (93.1)	44 (6.9)	
	Non-hypertensive co-morbidities	185 (74.0)	65 (26.0)	χ^2= 73.790 p = 0.000
	No co-morbidity	1329 (90.5)	140 (9.5)	
Chronic kidney diseases	Present	08 (21.1)	30 (78.9)	
	Non-CKD co-morbidities	775 (90.7)	79 (9.3)	χ^2= 191.210 p = 0.0000
	No co-morbidity	1329 (90.72)	136 (9.28)	

Table 3: Treatment outcome by socio demographics of the study subjects.

Variables	Subgroup	Treatment outcome		Significance
		Cured Number (%)	Died Number (%)	
Age group	< 18 yr	116 (98.3)	2(1.7)	
	18 to <60 yr	1496 (93.3)	107 (6.7)	χ^2= 123.713 p = 0.000
	≥ 60 yr	496 (78.0)	140 (22.0)	
Sex	Male	1165 (94.18)	172 (5.82)	χ^2= 2.495 p = 0.1142
	Female	940 (92.42)	77 (7.58)	
Residence	West Tripura district	1279 (88.7)	163 (11.3)	χ^2= 2.150 p = 0.143
	Other districts	829 (90.6)	86 (9.4)	
Religion	Hindu	2002 (89.3)	240 (10.7)	χ^2= 0.959 p = 0. 327
	Non-Hindu	106 (92.2)	9 (7.8)	

Death rate was found to be 5.8% among the recipients of first dose of COVID-19 vaccine, 9.3% among the recipients of second dose and 11.4% among those who did not receive any dose of the vaccine and these differences were found to be statistically significant. After combining the recipients of first and second doses together (Either partially or fully vaccinated) the death rate was observed as 7.4% among the vaccinated and 11.4% among the unvaccinated and this difference was also statistically significant (p<0.05).Table 1

Study subjects who had some form of co-morbidities had a death rate of 12.2% and it was 9.6% among those who did not have any co-morbidity. Patients having associated chronic kidney disease had a death rate of 78.9%, patients with co morbidities other than kidney disease had a death rate of 9.3% and those who did not have any co-morbidity had a death rate of 9.28%. All these observed differences were found to be statistically significant (p<0.05).Table 2

Highest death rate i.e. 22% was observed among the patients aged 60 years and above and least was found among patients aged less than 18 years. Difference in the death rate across different age groups was found to be statistically significant (p<0.05). Higher death rate was also observed among the female patients, residents of West Tripura district and those who were Hindu by religion, but statistically these were not significant (p>0.05).Table 3

Binary logistic regression analysis showed that with one year increment in age a COVID-19 patient had 5.5 % higher chance of death in the DCH (OR = 1.055, 95% CI = 1.044 – 1.067, p = 0.000), similarly with one unit increment in

Table 4: Result of binary logistic regression analysis.

Continuous variables		Odds ratio (95% C.I.)	p - value
Age		1.055 (1.044 – 1.067)	0.000
Oxygen saturation during hospitalization		0.874 (0.856 – 0.893)	0.001
Categorical variables		**Odds ratio (95% C.I.)**	**p - value**
Sex	Female	1	0.105
	Male	0.748 (0.526– 1.063)	
Residence	West Tripura district	1	0.768
	Other districts	1.054 (0.743 – 1.495)	
Vaccination status	Un-vaccinated	1	0.019
	Full and partial	0.444 (0.061 – 0.966)	
Co-morbidities	Absent	1	0.446
	Present	1.648 (0.456 – 5.962)	
Kidney diseases	Absent	1	0.000
	Present	4.057 (4.014 – 5.133)	
Hypertension	Absent	1	0.000
	Present	5.195 (3.356 – 8.040)	
Diabetes	Absent	1	0.000
	Present	2.730 (1.740 – 4.283)	

the blood oxygen saturation level during hospitalization, a COVID-19 patient had 87.4% lesser chance of death (OR = 0.874, 95% CI = 0.856 – 0.893, p = 0.001). Vaccination against COVID-19 showed 44.4% protective effect against death and it was statistically significant (p < 0.05). Likewise, COVID-19 patients with coexistent hypertension, diabetes mellitus and chronic kidney disease had significantly higher chances of death in the DCH (p < 0.05).Table 4

4. Discussion

Advisory panel from World Health Organization (WHO) recommended 50% vaccine efficacy for at least 6 months post-vaccination as a minimal criterion to define an effective vaccine.[15] A vaccine with an efficacy more than 50% can markedly reduce the incidence of COVID-19 among vaccinated individuals and help to build herd immunity. The US Food and Drug Administration (FDA) defines vaccine success criteria as a point estimate of vaccine efficacy at least 50% and the interim-monitoring adjusted lower bound of the 95% confidence interval exceeding 30%.[16]

Through our research, we aimed to investigate the variation of Covid-19 disease severity and treatment outcomes with respect to various socio-demographics along with their vaccination status. We also wanted to look into how certain co-morbidities would affect the same. In this study, the mortality rate among the study participants was found to be 10.56%. Review of literature shows that different publications have reported varying estimates of the mortality rate among hospitalized patients. In an observational study conducted in Germany involving 1904 COVID-19 patients hospitalized between February 12 and June 12, 2020, the mortality rate was found to be 17%.[17]

Another nationwide study from China involving 1590 hospitalized cases reported the mortality rate to be 3.2%.[18]

According to the Abu Dhabi Department of Health, the case fatality rate among all confirmed cases of COVID-19 in the United Arab Emirates was 0.33% as of December 8, 2020.Since this present study only involves hospitalized patients who had likely experienced relatively more severe disease courses, the mortality rate among those included in our study is supposed to be higher. According to one study older age was related to worse clinical outcomes in COVID-19,[19] but our study shows that 68% of the total participants are below 60 years compared to what had been reported in Oman.[20] Only 5% of our study patients are below the age of 18 years which is close to what had been observed from the first case of Covid-19 reported in Wuhan where they reported no clinical cases in children below 15 years of age.

In this present study 79.4% of study participants have not received any doses of Covid-19 vaccine whereas 20.57% are either partially or fully vaccinated. Among the vaccinated participants 92.6% completely recovered while 7.4% died, whereas among the unvaccinated, recovery rate is 88.6% and mortality rate is 11.4%. This implies that COVID-19 appears to be less severe in vaccinated as compared to unvaccinated individuals. According to our study, comorbidities like impaired Kidney function play an important role in treatment outcome of the admitted patients. Among the kidney patients mortality rate was very high (78.9%). This increased risk of post-vaccination infection among people with kidney disease could reflect increased exposure or impaired immunogenicity. This is supported by a study regarding humoral and B-cell responses in vaccinated, immune-suppressed kidney transplant recipients and patients having dialysis.[21] However, this finding should be interpreted cautiously because of the relatively small numbers of participants with kidney disease in this study.

5. Conclusion

Present study has found that old age, diabetes mellitus, hypertension and chronic kidney disease have got enhancing effect up on death due to COVID-19. On the other hand, vaccination against COVID-19 has shown significant protective effect against death due to COVID-19.

6. Limitations

Present study have some limitations that being a hospital based study it might be reflecting a controlled scenario and some cases might have failed to get admitted in the DCH due to lack of transportation, financial constrains, or other COVID-19 related discriminations.

7. Source of Funding

8. Conflicts of interest

There is no conflict of interest.

9. Acknowledgement

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