Covid-19 Morbidity amongst Covishield Vaccinated vs Non-Vaccinated: A Comparative Study

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ABSTRACT

Introduction: Covid-19 pandemic is further spreading its leg in India. Indigenous Covishield vaccination drive was started to protect people from the disease.

Objective: This observational cross sectional study was conducted to assess the morbidity and mortality pattern amongst Covishield vaccinated people Vs non-vaccinated patients of covid19.

Methodology: This observation study was conducted in a dedicated covid-19 hospital. All RTPCR covid-19 patients were included. The data on vaccination against covid-19 amongst the patients was obtained, and analysed using statistical software.

Results: The study population comprised of 155 cases of confirmed covid-19 patients of which 24 (15.48%) were fully vaccinated, however 41 (26.45%) and 90 (58.06%) were partially and non-vaccinated respectively. Fully vaccinated people were protected from development of severe form of disease (p=0.0083). Mortality was significantly less amongst vaccinated group (p= 0.028).

Conclusion: Patients who are completely vaccinated with Covishield vaccine are protected from development of severe form of diseases and deaths and hence mass vaccination of Indian population to overcome the pandemic is required at the earliest.

Key words: Covid-19, Covishield vaccine, herd immunity, fully immunized, non-vaccinated

INTRODUCTION

In December 2019, a large number of pneumonia cases of unknown origin emerged in Wuhan, Hubei province, China[1,2] and on January 3, 2020, a novel member of enveloped RNA corona virus was identified from a patient and thereafter confirmed as the cause of this disease.[3-5] The WHO named the disease associated with 2019-nCoV the 2019 novel corona virus disease (COVID-19).[6] Covid-19 is highly contagious disease and in country like India with dense population, the probability of people coming in contact with infected person and subsequently getting infected is very high.[7]

There is no definitive treatment for the disease, even though some advancement in management of cases has occurred and latest guidelines are being issued by health departments.[8–12] Still gaps exist in the knowledge of epidemiology of the disease and the safest way to prevent the disease is by attaining the herd immunity through vaccination.

Development of vaccines can be the most prominent approach to prevent the virus to cause COVID-19 and hence will play a vital role in controlling the spread of the virus and reducing mortality.[13] Vaccines have been widely considered as part of the exit strategy to enable the return to previous patterns of working,

schooling and socializing. Importantly, to effectively control the COVID-19 pandemic, production needs to be scaled up from a small number of pre-clinical doses to enough filled vials to immunize the world's population, which requires close engagement with manufacturers and regulators. It will require a global effort to control the virus, necessitating equitable access for all countries to have effective vaccines.[14] An efficacious vaccine is considered essential to prevent further morbidity and mortality.[15] In their target product profile for COVID-19 vaccines, WHO suggested that a "clear demonstration of efficacy (on a population basis) ideally with ~50% point estimate" should be a minimum criterion for any acceptable COVID-19 vaccine, and that efficacy can be assessed against "disease, severe disease, and/or shedding/transmission" endpoints.[16-18]

Vaccination drive started in India on 16 Jan 2021 and aimed at vaccinating 300 million populations in initial phase of vaccination including health care workers and frontline workers (police, army, sanitation worker etc). Vaccination in India started with 2 Types of vaccine Covishield and Covaxin.[19]

Covishield is locally manufactured in India by serum institute of India which is the Oxford-Astra Zeneca COVID 19 vaccine (AZD1222 or ChAdOx1).[20] Covishield vaccine found to have efficacy around 70.4%.[21] Covishield vaccine is safe and reported with few symptoms post vaccination which are mild and self-limiting and were reported 2-4 days after vaccination.[22] Most common symptoms were reported to be fever, myalgia, tiredness, headache, chills.[23]

With this background, the Objective of the study is to determine morbidity and mortality pattern amongst Covishield vaccinated and non-vaccinated Covid-19 positive patients.

SUBJECTS AND METHODS

This is an observational cross-sectional study conducted in a dedicated COVID-19 hospital of a government organisation situated in the Darjeeling dis-

trict of West Bengal. All employees and their dependents are the clientele of the hospital. Data on all COVID-19 patients admitted to the hospital between March 15 and May 5, 2021 were gathered from hospital records. No Covid-19 patients admitted to the hospital before the start of the study period.

All patients who tested positive for Covid-19 by RTPCR in an ICMR-approved lab were considered Covid-19 positive. All patients who were treated by the hospital were included in the study.

The vaccination status of the patients was determined as whether they were fully vaccinated (having taken 2 doses of the Covishield vaccine), partially vaccinated (having taken only one dose of the Covishield vaccine), or non-vaccinated (no vaccines taken). Cases who were treated as "isolated" (did not require any intervention except oral medicine) were classified as mild, and those who were treated in intensive care units (ICU) and high-definition units (HDU) were grouped as moderate-severe.

Microsoft Excel 2019 was used to compile and analyse the data. All individuals who have taken the COVID-19 vaccine other than COVIShield were excluded from the study. Ethical approval from the institutional ethics committee was obtained.

RESULTS

There was no case who had taken a vaccine other than Covishield.

A total of 155 cases of confirmed covid-19 were detected and treated by the hospital. Male preponderance was seen amongst the patients, with males contributing 84% (130) of total cases due to peculiarity of the clientele population which was predominately male. Most of the cases (94) were symptomatic (60.64%), while rest of the cases (61) was asymptomatic (39.35%). Maximum number of cases (86) were observed in the age group 18-45 years (56.57%), while age groups less than 18 years, 45-60 years and greater than 60 years had 6 (3.87%), 40 (25.8%) and 23 (14.83%) respectively.

Table 1: Age wise distribution of Covid-19 cases

Age groups (years)	Sex		Symptoms		Total cases (%)	Deaths (%)
	Male (%)	Female (%)	Yes (%)	No (%)		
<18	4 (66.66)	2 (33.33)	4 (66.66)	2 (33.33)	6 (3.87)	0
18-45	73 (84.88)	13 (15.11)	55 (63.95)	31 (36.04)	86 (55.48)	0
45-60	34 (84)	6 (15)	18 (45)	40 (25.80)	40 (25.80)	4(28.57)
>60	19 (82.60)	4 (17.39)	10 (43.47)	23 (14.83)	23 (14.83)	10 (71.43)
Total	130 (83.87)	25 (16.13)	94 (60.64)	61 (39.35)	155 (100)	14 (100)

Table 2: Distribution of cases as per vaccination status and severity of illness

Vaccination status of patients	Isolation (Mild) (%)	ICU/HDU (Moderate-Severe) (%)	Total (%)
Fully vaccinated	20 (19.23)	4 (7.8)	24 (15.48)
Partially vaccinated	33 (31.73)	8 (15.68)	41 (26.45)
Non-vaccinated	51 (49.04)	39 (76.47)	90 (58.06)
Total	104 (100)	51 (100)	155 (100)

(X^2 =9.57, df =2, p=0.0083. Odds ratio: vaccinated and non-vaccinated groups = 0.2961 (protective), 95% CI= 0.1395 – 0.6285)

Table 3: Mortality rate in study groups

Vaccination status	Total cases (%)	Total Deaths (%)	Mortality rate	Outcome	
				Fatal	Non-fatal
Fully vaccinated	24(15.48)	0	-	02	63
Partially vaccinated	41(26.45)	2(14.29)	4.88		
non-vaccinated	90(58.06)	12(85.71)	13.33	12	78
Total	155(100)	14	9.03	14	141

Vaccinated vs. non-vaccinated group: X^2= 4.83, p=0.028, d.f= 1; Odds ratio= 0.206 (protective), 95% CI= 0.0445-0.9562

When we compare the mortality in each age groups, we observe that the maximum deaths (10) are contributed by the >60 age group (77%) followed by 45-60 years age group (4) (28.57%). Most of deaths (9) where observed to have co-morbidities (64.28%). It was also observed in one instance that severe Covid-19 amongst 02 members of same family with fatal outcome.

It was observed that the severe diseases developed mostly amongst non-vaccinated participants (39, 76.47%) followed by partially vaccinated individuals (8, 15.68%). The severity of development of Covid-19 was analysed with the vaccination status of patients using chi square test. There was significant difference between the groups ($X2 = 9.57$, df=2, p= 0.0083).

It is observed that the mortality rate amongst the non-vaccinated is very high (13.33%). When the data was analysed using Chi Square test to determine the difference between the deaths amongst partially vaccinated and non-vaccinated, the difference was not found to be significant ($X^2 = 2.11$, p= 0.15, d.f =1). However when the data was analysed to determine the difference in mortality rates amongst non vaccinated with those who were vaccinated (taken either 1st or both doses) using chi-square test, the result were found to be significant ($X2=4.83$, p=0.028, d.f=1).

DISCUSSION

The reason for the age groups 18-45 years and 45-60 years contributing the maximum covid-19 cases is probably due to the fact that this is the working population and also the most active[24], hence chances of infection are high and vaccination of the individuals was done as per the government guidelines.

The mortality rate amongst elderly seems to be alarming. The presence of co-morbidities and low immune status probably may be the contributing factors for such high death rate amongst elderly.[25] However, this cannot be justified only based on this basis, other possibility like mutated virus with high virulence and only serious cases reporting to the hospital may be also the contributing factor. This need to be researched on larger sample size or by meta-analysis. We believe that there may be some genetic composition involved in development of severe form of disease[26] as the blood relatives of a family were observed to develop severe infection.

However this also needs to be researched further in larger studies.

It is clearly evident from the study that outcome of the vaccination is rewarding. Those who are non-vaccinated are at a higher risk of getting severe form of covid-19. Covishield vaccine is found to be effective in preventing the development of severe form of the disease and deaths due to the disease.

There is rare occurrence of no deaths amongst fully vaccinated till now but this may change if the data is larger, hence the mortality rate cannot be commented upon. However it is clearly evident that fully vaccinated people are definitely protected from development of severe form of disease and deaths. Moreover, even one dose of vaccination is observed to be providing protection from the deaths due to Covid-19. However, statistically no difference was found in mortality rates of non-vaccinated and among partially vaccinated. Since one dose vaccination does not offer significant protection, people should be educated and protected from false sense of security after one dose of covishield vaccine. This requires a massive effort quickly in India to immunize maximum population with two doses of vaccine to attain herd immunity. However percentage of population required to be vaccinated to attain the herd immunity is yet to be determined, hence efforts should be made to immunize near to 100% population as early as possible. Prioritization of vaccination to elderly and those with co-morbidities is required as maximum fatalities have been observed in this age group. The duration of protection against the virus offered by the vaccine is still not known. However if we presume that it is around 1 year like any other flu vaccines than booster doses will be required every year extending the burden and challenges to maintain herd immunity in a vast country like India. Hence capacity building is to be done to escalate the vaccine production so that mass vaccination can be done. As we have an effective vaccine in India against novel-corona virus we need high level of political commitment, augmentation of vaccine supply, involvement of frontline workers like ASHA and ANM in the vaccination process to speed up the vaccination process and attain the herd immunity in the country. This is the only tool to prevent subsequent waves of covid-19 and save millions of lives. However since virus has capability to mutate rapidly and there is no safe vaccine yet available for children, efforts should be made to develop a safe and effective vaccine for the children also. We may

have to incorporate the vaccine in the routine immunization programme for the children and hence preparations should be started as early as possible. At the same time research is required to be carried out to determine the cure for the disease as it is highly predictable that the disease may become endemic to various parts of the world. Hence its eradication will require international, national, local and individual level efforts.

CONCLUSION

Based on the findings of the research we conclude that the covishield, the indigenous vaccine against covid-19 developed by India offers sufficient protection from development of severe form of the disease. However the duration of protection offered by the vaccine could possibly be short like any other influenza virus, hence requirement of booster doses will be a necessity in future. Capacity building and micro planning to streamline the process of vaccination and boosters amongst all age groups in Indian population, to prevent future outbreaks, is the need of the hour.

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