Study on Safety, Efficacy & Outcomes of Covid-19 Vaccines in Healthcare and Front-Line Staff

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Abstract
Introduction: *COVID-19 vaccine development has taken an expeditious pace to be made available for the public. However, there remains a sense of hesitancy in the public towards the vaccine due to few reported adverse reactions. The current study aims to analyze clinical outcomes of the beneficiaries who took the COVID-19 vaccine to provide a better picture on their efficacy, safety, and immunogenicity.*
Methods: *Participants (14,803) who took part in the study belonged to two organizations, viz. Medicover Group of Hospitals, India who are mentioned as healthcare staff in this study (8759) and the Police staff of Cyberabad Commissionerate, Telangana mentioned as frontline staff (6044). Data was collected using a survey instrument i.e., structured questionnaire. The questionnaire had two parts, including gender, age, level of education, and questions regarding incidence and severity of post-vaccination reactions after vaccination against COVID-19 .Vaccines considered in the study were Covishield and Covaxin. Data collected in this study were analyzed using descriptive statistics.*
Results: *A total of 921 and 691 COVID-19 cases were reported during the 1st and 2nd waves of the pandemic in the front-line staff, where the majority recovered without the need of hospitalization in 2nd wave. Among the infected healthcare staff (908) in the 1st and 2nd waves, least number (270) were observed in the 2nd wave. Majority of the frontline (5025) and healthcare (7817) staff were completely vaccinated during the continuous vaccination drives through Jan 2021–May 2021. The most common symptoms post-vaccination were mild rise in temperature (2104) and myalgia (1874). All the post-vaccination admitted staff (126) were recovered without the need for ICU admissions.*
Conclusion: *Population considered for this study, both healthcare and frontline staff, is at constant exposure to multiple strains of virus ranging in their virulence and from different geographical locations. Under these distressing circumstances, COVID vaccines have given a safe cover to the staff from this dreadful pandemic.*

I. Introduction

COVID-19 vaccine development has taken an expeditious pace to be made available for the public, with endless efforts into its research and development by the manufacturers. Despite promising literature on its safety and efficacy amidst the pandemic, 28.7% of people were hesitant across the nation to get inoculated. The current study is systematically reviewed, summarized and meta-analyzed with the clinical outcomes of the beneficiaries who took the COVID-19 vaccine to provide a better picture on their efficacy, safety, and immunogenicity.[1]

Vaccine development and rollover to public can take several years through strenuous clinical trials. Global scientific team has made continuous efforts to make the COVID vaccines available in less than a year as a ray of hope amidst this pandemic. Despite the imperative measures by the Indian Government in making the COVID-19 vaccine available at a remarkable pace to public, hesitancy with regards to their safety, efficacy and outcomes has taken a toll in the initial phases of vaccination campaign.

COVID-19 vaccination drive in the country has been initiated from 16 Jan 2021 with priority to the Healthcare staff and then to the Frontline staff. Vaccination for citizens above 60 years and 45–59 years with listed co-morbidities were started from 01 Mar 2021 onwards. Further, vaccination for the citizens above 45 years was started from 01 Apr 2021, and from May 2021 it has been rolled out for 18+ year adults. As on date, India has vaccinated 26,11,47,292 people with vaccination drives spread around 31,235 centers across India in both Government and Private organizations.[1, 2]

Significance

People were indecisive of COVID-19 vaccines due to their concerns on safety, efficacy and outcomes resulting in lot of hesitancy among people to choose upon which vaccine to take despite of the encouraging

results in the preclinical studies. With this study we want to reveal the results to the public regarding the importance, safety, efficacy and outcomes of COVID-19 vaccination, which we have witnessed among the extremely high-risk groups i.e., healthcare and the front-line staff.

II. Materials and Methods

Study population and data collection

Participants who took part in the study belonged to two organizations, *viz*. Medicover Group of Hospitals, India who are mentioned as healthcare staff in this study and the Police staff of Cyberabad Commissionerate, Telangana mentioned as frontline staff.

Total sample size for the study was 14,803 (8759 Healthcare staff – Employees of Medicover group of Hospitals, India and 6044 Frontline staff – Police personnel of Cyberabad Police Commissionerate, Telangana).

Data was collected using a survey instrument i.e., structured questionnaire. An anonymous study was conducted with a structured questionnaire among healthcare staff of Medicover Hospital across all the units in India and among the frontline staff of Cyberabad police, Telangana. All the parameters of the questionnaire were anonymous, so that the respondents can give their opinion freely and genuinely. The first part of both the questionnaires covers demographic profile of the participants including gender, age and level of education. The second part pertains to questions regarding incidence and severity of post-vaccination reactions after vaccination against COVID-19, which were binomially scaled, and the responses are systematically reviewed.

Vaccines considered in the study are both Covishield and Covaxin. Data collected in this study were analyzed using descriptive statistics.

Ethical considerations

No respondent was forced to participate in the study. The full details of the study were discussed with them before they take part in it. The names of the respondents were not asked nor if ever stated, will be disclosed as the tool was anonymous to get genuine opinion.

III. Results

Questionnaires were distributed among the study population of healthcare staff (n = 8759), which included Doctors, Nurses, Pharmacy staff, technical staff, and supportive staff, and also distributed among front-line staff (n = 6044) of Cyberabad police, Telangana, who were a part of COVID-19 vaccination drive since 16th January 2021 to 31st May 2021.

Frontline workers COVID-19 infection in 1st & 2nd wave

Table 1: *Front-line workers during 1st & 2nd wave of COVID pandemic*

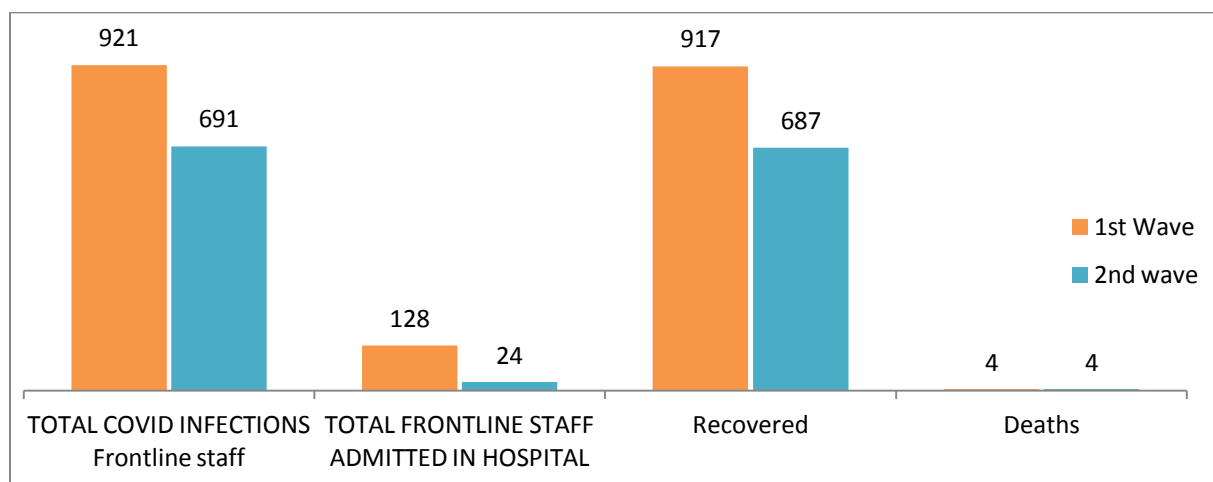| Covid-19	Total covid cases	Total front-line workers admitted in hospital	Recovered	Death
1st wave	921	128	917	4
2nd wave	691	24	687	4

Figure 1: *Represents the data of front-line staff infected with COVID 19 during wave 1 and wave 2 of the pandemic*

There were a total of 921 COVID-19 cases reported during the 1st wave in front-line staff, of which 793 were of mild category,128 were admitted in the hospital with moderate disease, and 4 deaths were observed.
In the 2nd wave, 691 cases were reported, of which 663 recovered without the need of hospitalization, 24 were admitted in the hospital, and 4 succumbed to the disease (Figure 1, Table 1).

Health care staff COVID-19 infection in 1st & 2nd wave

Table 2: *Healthcare staff during 1st Wave and 2nd Wave of COVID pandemic*

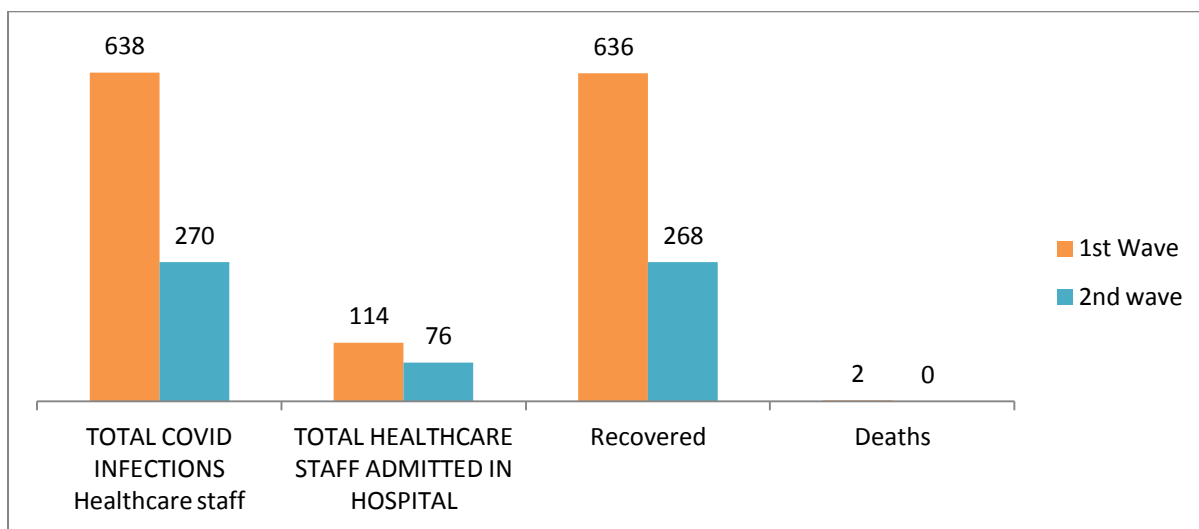| COVID-19	Total COVID cases	Total healthcare staff admitted in hospital	Recovered	Death
1st wave	638	114	636	2
2nd wave	270	76	268	2

Figure 2: *Healthcare staff during 1st Wave & 2nd Wave of COVID pandemic*

During 1st wave 638 healthcare staff were infected of which, 114 were admitted, 636 recovered and 2 are succumbed to the disease. In 2nd wave, 270 healthcare workers got infected in which, 76 were admitted to the hospital, 268 recovered, and there were 2 deaths.

Vaccination history in healthcare and front-line workers

Table 3: *Vaccination History*

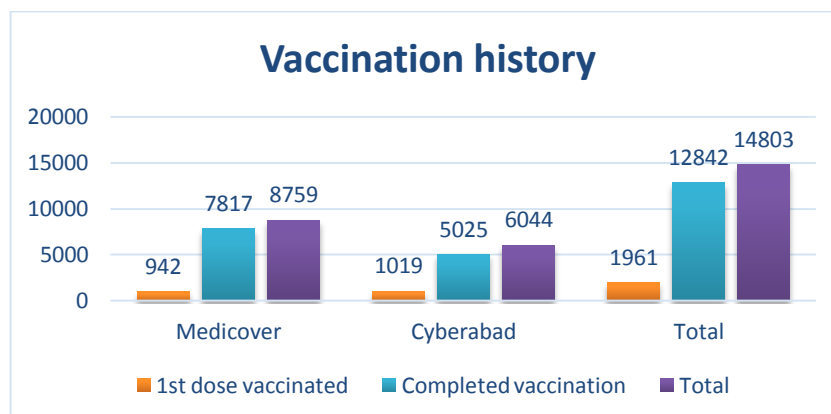| Vaccination History	Medicover	Cyberabad	Total
1st dose vaccinated	942	1019	1961
Completed vaccination	7817	5025	12842
Total vaccinated	8759	6044	14803

Figure 3: *Vaccination History*

Figure 3 represents vaccination history of Medicover Hospitals and Cyberabad police staff. Among a total of 9270 Medicover staff, 942 staff received 1st dose and 7817 received 2nd dose. Of the 6346 Cyberabad police personnel, 1019 and 5025 received 1st and 2nd doses, respectively (Table 3, Figure 3).

Post-vaccination infection

Table 4: *Total staff Infected post-vaccination*

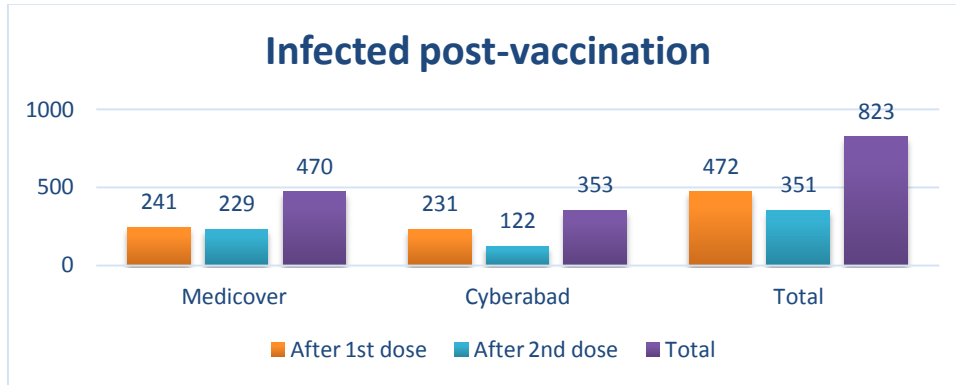| Total infected	Medicover	Cyberabad	Total
After 1st dose	241	231	472
After 2nd dose	229	122	351
Total	470	353	823

Figure 4: *Post-vaccination infection history in Medicover Hospital and Cyberabad Police Staff.*

Of the total 470 Medicover Hospital staff infected, 241 staff were infected after 1st dose and 229 infected after 2nd dose. Out of the 353 Cyberabad police staff, 231 and 122 were infected after 1st and 2nd doses, respectively (Table 4, Figure 4).

Table 5: *Admissions post-vaccination*

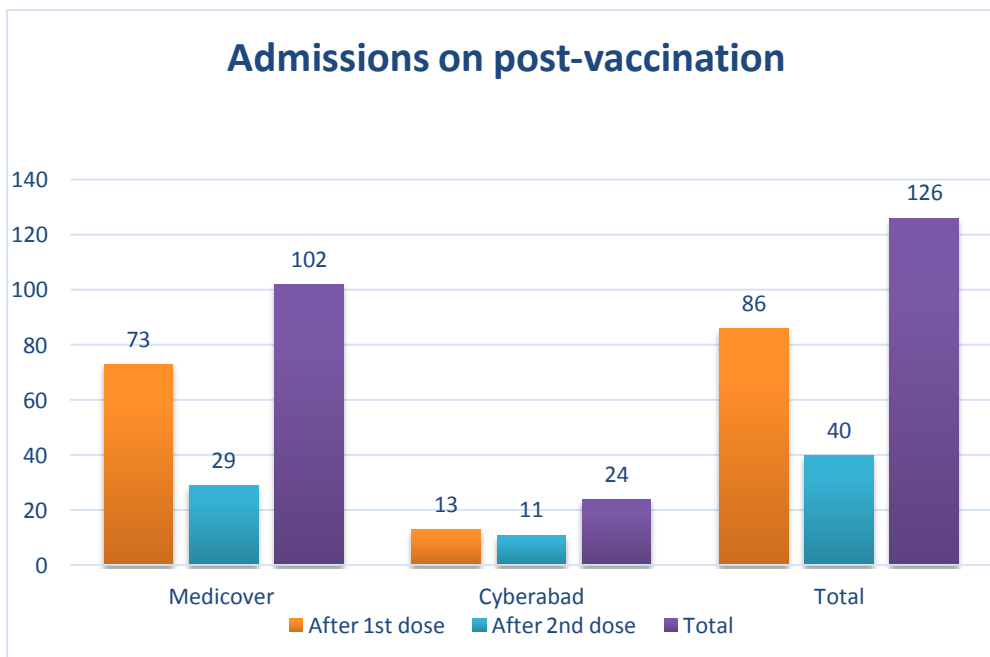| Admissions	Medicover	Cyberabad	Total
After 1st dose	73	13	86
After 2nd dose	29	11	40
Total	102	24	126

Figure 5: *Admissions after post-vaccination*

A total of 102 Medicover Hospital staff who got vaccinated and infected in the later course were admitted. Of which, 73 and 29 people were admitted after 1st and 2nd doses, respectively. Out of a total of 24 Cyberabad police staff, a total of 13 staff were admitted after 1st dose and 11 staff got admitted after the 2nd dose (Table 5, Figure 5).

Table 6: Side effects

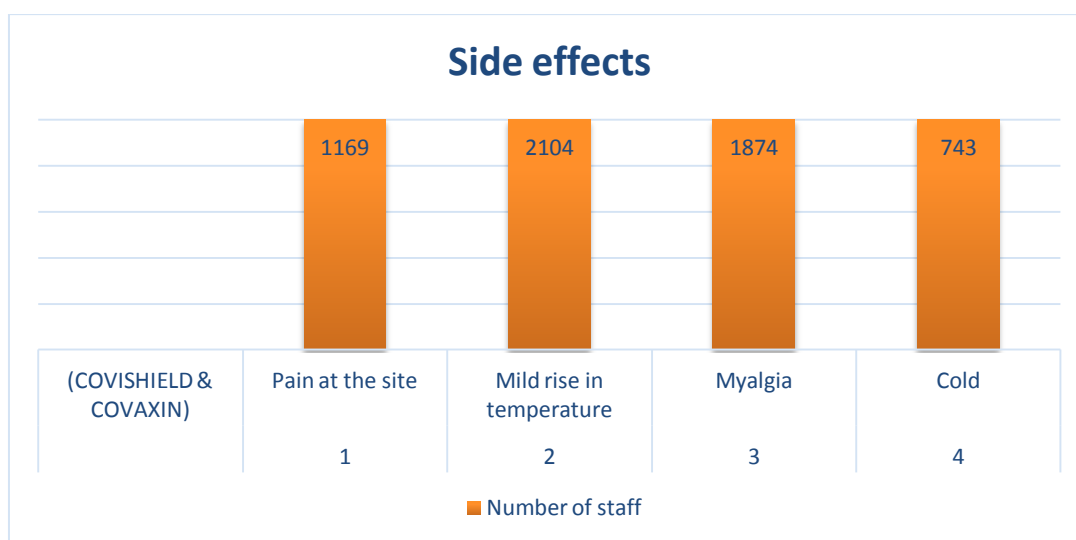| Sl. No.	Side effects (COVISHIELD and COVAXIN)	Number of Personnel
1	Pain at the site	1169
2	Mild rise in temperature	2104
3	Myalgia	1874
4	Cold	743

Figure 6: Side effects

The side effects of Covishield and Covaxin were as represented in Table 6. Of the total vaccinated staff, 1169 had pain at the site of injection, 2104 presented with mild rise in temperature, 1874 had myalgia, and 743 had cold (Figure 6).

All the admitted healthcare and front-line staff were having only mild degree of infection and no one among the vaccinated staff showed symptoms of moderate/severe category of disease with no conversion of admissions to Acute Care units and no deaths were reported among the vaccinated.

Unfortunately, we have lost 12 staff in the battle against the pandemic (4 healthcare and 8 frontline staff), who were not vaccinated even with the single dosage of vaccine.

IV. Discussion

We conducted study on safety and efficacy on front-line workers of Cyberabad Police Commissionerate and healthcare workers of Medicover Group of Hospitals all over India after taking 1st and 2nd dose of COVID-19 vaccine.

Since the emergence of the novel corona virus disease (COVID-19), which is caused by SARS-Cov-2 in 2019, researchers have been on the move to find solutions to mitigate the spread of the virus. Various control measures have been put in place by governments under guidelines and recommendations of key global agencies with the world health organization (WHO) leading in providing information to help fight the pandemic. This paper is geared towards providing a detailed review and analysis of developments of the current vaccines in terms of safety and efficacy.

In a study conducted by Nepal Government on efficacy of vaccines in front-line workers and healthcare workers, some health workers complained about irritability in mood after four hours of vaccination, and some complained of myalgia, nausea, tenderness at the injection site and feverish feeling after six hours of vaccination. After 12 hours, fever with chills developed, which required Paracetamol to resolve. Comparatively, our study also has shown the same symptoms after 4 hours of vaccination and subsided after 72 hours.[2]

In one of the studies conducted by Fortis CDOC Center of Excellence for Diabetes, Metabolic Diseases & Endocrinology, New Delhi, India, out of 123 employees [males 75, females 48; mean age: 42yrs (range 22-70y)], 113 were vaccinated (Covaxin, 28, Covishield, 85). Second dose was completed in 107 (94.7 and first dose in 6 persons (5.3%). Symptomatic COVID-19 infections occurred in 19/113 persons (16.8%), 18 of them had incurred it after the second dose after a mean of 34.8 days. Twelve persons among these were less than 40 years of age. Breakthrough symptomatic COVID19 infections (14 days after the second dose) occurred in 15 persons (13.3%). All were symptomatic with fever and half of them had sore throat and cough. A few had loose motions and loss of smell and taste. Symptoms lasted from 3 to 14 days. Except one (required hospitalization for COVID-19 pneumonia), all 14 persons with breakthrough infections had mild COVID19 disease.[3] Comparatively, our study shows 1.1% of Medicover staff were infected of which, 71% were admitted after1[st] dose and 28% admitted after 2nd dose. A maximum of 0.3% of Cyberabad police staff were infected, of which 54% were admitted after 1st dose and 45% were admitted after 2nd dose.[3]

Following vaccination, it was analyzed among all the staff (both healthcare and frontline) for the adverse effects followed by vaccination, significant side effects reported after the vaccination within 72 hrs. included pain at the site (n = 1169), mild rise in temperature (n = 2104), myalgia (n = 1847) and cold (n = 743). All of these were addressed by our doctors *via* tele consultation, and all the side effects subsided after 72 hrs. Both the vaccine manufacturers in the study (COVISHIELD and COVAXIN) were informed about the occurrence of common side effects in their fact sheets followed by the inoculation of vaccine.[4-6]

Healthcare staff included a variety of occupations with varying levels of education. Several aspects were observed during the study regarding the importance of education and the ability to recognize correct information about the COVID-19 vaccine. There was a hesitancy observed in the staff during initial phases of the vaccination campaign with the limited studies available on their outcomes, but most of them got vaccinated eventually. Our Infection control team has made continuous sessions among healthcare staff particularly to the sanitation and security staff to bring the awareness on the importance of vaccination.

Before the vaccination campaign started in India, we have seen unpleasant scenario among the healthcare staff as well as the frontline staff. Duties of both the categories of staff are indispensable and once infected; they have to go through the required quarantine period. This also brought lot of emotional stress on their colleagues to work in such a high-risk environment. Even the Indian Government made all the necessary efforts to rollout the vaccine into the country, and they have made it available on priority to the healthcare and frontline category of staff.

There was a clear change in mindset of the staff after getting vaccinated with 2 doses of vaccine and it also contributed to making the people to rethink about their hesitancy towards vaccination. We have achieved maximum success in vaccinating our staff.

Obtained results from our study clearly reveal the safe coverage and efficacy of COVID vaccines among the vaccinated. People in the Healthcare and Police departments have made relentless efforts to keep the pandemic at bay and the results observed among such high-risk group are promising to say that COVID vaccines observed in the study are safe and are required mandatorily to break the chain of this pandemic and will be an essential factor in decreasing future surges of COVID-19 infections.

Evidence-based approaches at all the levels are necessary to improve vaccination efforts and to decrease hesitancy. Educating the public about the safety of the current and forthcoming vaccines is of vital consequence to public health to vaccinate the maximum in country and to achieve the stage of herd immunity.

V.   Conclusion

It has been proven beyond and out that vaccination works. We have witnessed scenarios like 1st and the 2nd wave of the COVID-19 pandemic; wherein the Corona virus had affected huge number of people and with the availability of vaccines around, Vaccination production & drives should ramp up on utmost priority for vaccinating the people thereby leaving no set of vulnerable population to get affected. We need to vaccinate everyone with no matter which ever vaccine it is available, disregarding which we may have to face serious threats if at all there is any 3rd wave coming.

Population considered for this study, both healthcare and frontline staff, is at constant exposure to multiple strains of virus ranging in their virulence and from different geographical locations. In this kind of high potential exposure to the virus, they can amplify the outbreaks of disease if they become ill. Under these distressing circumstances, COVID vaccines have given a safe cover to the staff from this dreadful pandemic.

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