



Safety of Covishield Vaccine After Prime and Booster Dose in Front Line Warriors of Warangal District

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Abstract

Background: The study is to assess the safety of COVISHIELD vaccine in front line warriors receiving prime and booster dose. **Aim:** The aim of this study is to evaluate safety of COVISHIELD vaccine. **Methodology:** A prospective observational study was conducted in vaccination centers in a tertiary care teaching hospital for a period of 6 months. All the front-line warriors who received prime and booster doses were included in the study and reviewed. **Results:** Overall all safety parameters were collected, out of which subjects with Hypertension are 16 (11%), Diabetes Mellitus 14 (9.60%), Fever 141 (97.10%), Injection Site pain 145 (100%), Rise in B.P 12 (8.20%), Headache 88 (60.60%), Nausea 38 (26.20%), Decreased appetite 28 (19.30%), Fatigue 68 (46.80%), Myalgia 65 (44.80%), Itching & Redness 18 (12.40%), Skin Rashes 16 (11%), Anosmia & Ageusia 2 (1.30%), Blurred Vision 7 (4.80%), Dry Lips 1 (0.60%), Giddiness 34 (23.40%), Cold & Cough 43 (29.60%), Eye Pain 2 (1.30%), Numbness 11 (7.50%), Increased Salivation 3 (2%), Mental Status Disturbance 2 (1.30%), Tachycardia 4 (2.70%), Leg Pain 10 (6.80%), Back Pain 17 (11.70%), Neck Pain 5 (3.40%), Ulcers in mouth 3 (2%), Tooth pain 1 (0.60%), Epigastric Pain 5 (3.40%), Hypotension 7 (4.80%), Swelling of knee 2 (1.30%), Facial puffiness 5 (3.40%), Weight gain 6 (4.10%), Blister Development 2 (1.30%). **Conclusion:** Our study demonstrates that the COVISHIELD vaccine is highly effective against the novel corona virus. The results of our study suggest that people who received both prime and booster doses have shown good efficacy to vaccine without any severe adverse drug reactions. It was concluded that adverse effects which appeared after the dose received are not very severe, can be relieved within two or three days. Overall, the safety of the COVISHIELD vaccine was decent. Further investigations are required to study the long-term efficacy of the vaccine and long-term adverse effects after two doses of vaccine.

Keywords

Corona virus disease, COVISHIELD vaccine, prime and booster dose, COVID-19.

INTRODUCTION

Corona virus disease (covid-19) is a highly transmittable and pathogenic viral infection caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) which emerged in Wuhan, China, and spread around the World ^[1].

Corona virus belongs to the order Nidovirales in the family Coronaviridae. SARS-CoV-2 was closely related to the beta-corona viruses. The genome of SARS-CoV-2 is positive-sense single-stranded RNA [(+) ssRNA] with a 5'-cap, 3' UTR poly (A) tail. The length of the SARS-CoV-2 genome is less than 30kb in which there are 14 open reading frames (ORF), encoding non-structural proteins (NSPs) for virus replication and assembly processes, structural proteins including spike(S), envelope (E), membrane(M), nucleocapsid (N) genes and accessory proteins ^[2].

The novel corona virus disease (COVID-19) caused by SARS-CoV-2 emerged in Wuhan, China 2019. It has now spread to 210 countries around the world, and as of 1st February 2021 more than 100 million subjects had been infected. It has been noted that >2million have already died from SARS-CoV-2 ^[3]. The possible modes of transmission of SARS-CoV-2 include contact, droplet, airborne, fomite, fecal, oral, urine, saliva, and animal-to-human. SARS-CoV-2 is primarily transmitted between people via respiratory droplets, which can be produced through talking, coughing, or sneezing. ^[4].

The incubation period for COVID-19 which is the duration from exposure to the virus to the onset of symptoms is on average 5-6 days, it can be up to 14 days. The viral load and shedding pattern is different in each subjects. The virus can be detected one day before and peaks soon after the onset of symptoms and viral shedding time ranges from 8 to 37 days with a median of 20 days ^[5].

PATHOPHYSIOLOGY:

IMMUNE-MEDIATED INFLAMMATION:

i) Immune-mediated inflammation plays an important role in the pathogenesis of COVID-19. Subjects with severe COVID-19 showed lymphopenia, particularly a reduction in peripheral blood T cells while CRP, ferritin IL-6, IL-10, C-X-C motif chemokine 10 (IP10), monocyte chemoattractant protein 1 (MCP-1),

macrophage inflammatory protein 1 alpha (MIP-1 α) and TNF- α were markedly elevated ^[6].

ii) CD4+ and CD8+ T cell count decreased; however, these cells were highly activated during inflammation ^[7].

iii) **HOST RESPONSE TO SARS-CoV-2** ^{[8] [9]}:

The symptoms of subjects infected with SARS-CoV-2 range from minimal symptoms to severe respiratory failure with multiple organ failure. Epithelial cells, alveolar macrophages, and dendritic cells (DCs) are the three main components of innate immunity in the airway.

DCs reside underneath the epithelium. Macrophages are located at the apical side of the epithelium. DCs and macrophages serve as innate immune cells to fight against viruses till adaptive immunity is involved.

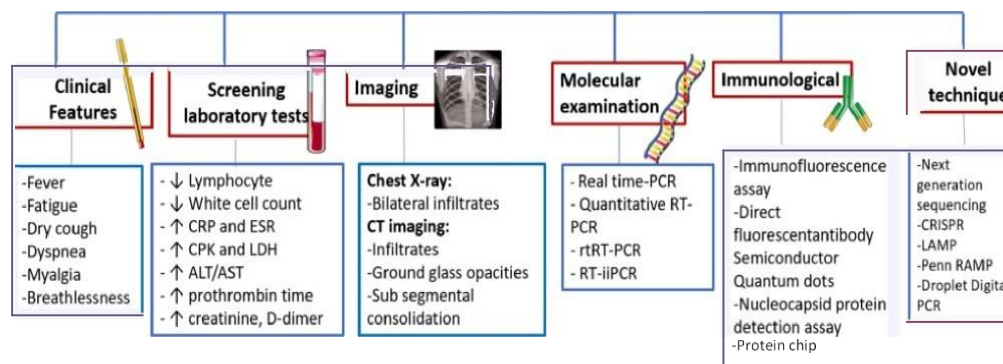
Microscopically, the main pathological changes in the lungs were.

- Increased number of macrophages in the tissue
- Serous fibrinous exudation
- Hemorrhage in some of the alveolar cavities
- Diffuse alveolar lesion.
- Alveolar degeneration
- Pulmonary consolidation

CLINICAL FEATURES AND DIAGNOSIS:

- The initial clinical symptoms of COVID-19 are similar to all types of viral pneumonia, with varying degrees of severity. Among the subjects showing symptoms of COVID-19, ~ 80% of subjects had a mild illness, 14% of subjects showed severe illness, and 6% of subjects developed critical illness requiring intensive care or mechanical ventilation assistance ^[10].
- Elderly people and people with co-morbidities such as Chronic obstructive pulmonary disease, Diabetes, Hypertension, and heart diseases have an increased risk of severe illness. Fever, cough, and shortness of breath were the first typical symptoms of COVID-19 pneumonia and later associated with fever, chills, muscle pain, sore throat, and loss of taste and smell perception ^[11].

Figure.1: Diagnostic protocol recommended for COVID-19



Treatment of COVID-19 should be selected based on the staging of the disease.

According to the WHO guidelines, if the patient's symptoms are mild, providing care at home may be considered as long as patient can be followed up and cared by family members. However, severe cases should be admitted to designated hospitals for proper treatment [12].

• **Treatment for the mild COVID-19 cases:**

The clinical symptoms of these cases are mild and there is no pneumonia manifested on chest imaging. Patients should stay in bed, which is the principle for treatment of mild COVID-19. cases. Blood oxygen saturation monitoring and oxygen therapy with nasal cannula should be conducted regularly for these subjects.

• **Treatment for the moderate COVID-19 cases:**

The clinical symptoms are moderate with fever, respiratory tract symptoms and pneumonia manifestations is observed on chest imaging. Treatment principles include bed rest, supportive treatment to maintain energy, water and electrolyte balance, and monitoring vital signs and oxygen saturation [13]. Subjects should be given oxygen therapy as needed. They can be provided with nasal cannula therapy. If this does not work, subjects should be treated with mask oxygen and cannula oxygen therapy.

Subjects should also be given antiviral therapy.

- Lopinavir/ritonavir- an approved antiviral drug that blocks the cleavage of Gag-Pol polyprotein.
- Ribavirin - synthetic nucleoside antiviral agent with a broad-spectrum antiviral activity that can inhibit DNA and RNA viruses.
- Redoxivir has shown a significant effect in the treatment of SARS and MERS infection.

- Remdesivir improves signs and symptoms significantly. In addition, antiviral drugs such as darunavir, abidor, and favipiravir can theoretically be used in the therapy of COVID-19 infection [14].

• **Treatment for the severe / critical COVID-19 cases:**

Severe cases have severe respiratory symptoms such as shortness of breath, a decrease of oxygen levels, and a decrease of PaO₂ / FiO₂. The general treatment principles for these cases are prevention and treatment of complications, prevention of secondary infections while treating basic diseases, and organ function support treatment promptly [15][16].

MATERIAL AND METHODS

Study design:

This is a prospective observational study which was conducted for 6 months in vaccination centers in Mahatma Gandhi Memorial Hospital, Warangal, Telangana, India.

Inclusion criteria

- People with aged >20yrs who received both prime and booster doses, people with history of covid-19 infection, people with chronic illnesses and several other co morbidities are included.
- All front-line warriors (health care professionals, nurses, police men etc.,) are included.

Exclusion criteria

- People with aged <20 who received only prime dose, several other co morbidities (such as CAD, ACS, respiratory problems), Pregnant and lactating women are excluded.
- People who faced hypersensitivity reactions with the prime (1st) dose and with active symptoms of covid-19 and People who have taken SARS –CoV -2 monoclonal antibodies (convalescent plasma) from SARS –CoV -2 subjects are excluded.

METHODS

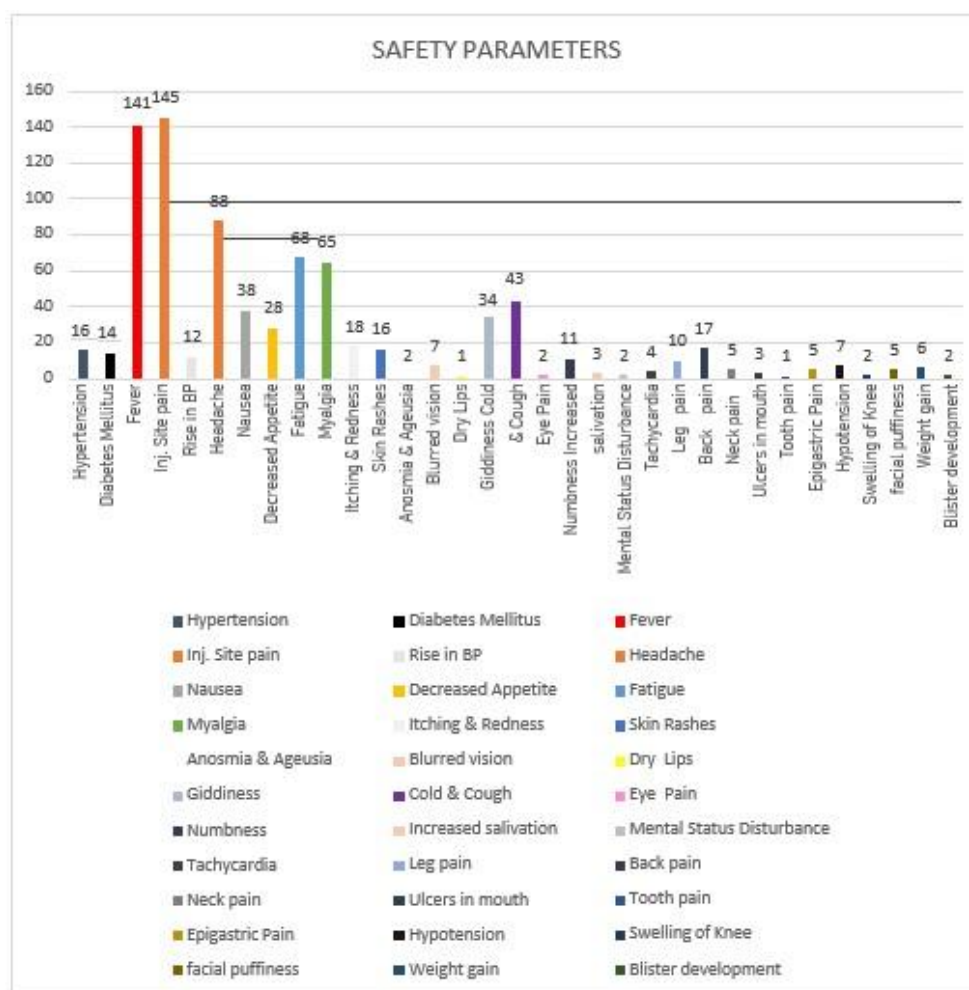
Our project protocol was submitted to the Institutional Human Ethics Committee (IHEC) and got approved prior to the initiation of the research work. Our approval number is IHEC / VCOP / PHARM.D / NRCT / 2020 / 012. The subjects included were 145 subjects with different types of safety parameters. Data collection tools were questionnaires. First, a safety parameter questionnaire was used which included personal characteristics like myalgia, pyrexia,

cramps, dyspepsia, epigastric pain, mild smell and taste perception, blurred vision, skin rashes, itching, swelling, arthralgia, pain at the site of vaccine administration, decreased appetite, decreased sleep, lymph node swelling, lethargy, fatigue, any psychiatric symptoms like anger, fearfulness.

Statistical analysis

The data was collected and analyzed using Microsoft Excel (Version 2019).

RESULTS



Overall, all safety parameters were collected out of which subjects with Hypertension are 16 (11%), Diabetes Mellitus 14 (9.60%), Fever 141 (97.10%), Insite pain 145 (100%), Rise in B.P 12 (8.20%), Headache 88 (60.60%), Nausea 38 (26.20%), Decreased Appetite 28 (19.30%), Fatigue 68 (46.80%), Myalgia 65 (44.80%), Itching & Redness 18 (12.40%), Skin Rashes 16 (11%), Anosmia & Ageusia 2 (1.30%), Blurred Vision 7 (4.80%), Dry Lips 1 (0.60%), Giddiness 34 (23.40%), Cold & Cough 43(29.60%), Eye Pain 2 (1.30%), Numbness 11 (7.50%), Increased Salivation 3 (2%), Mental Status Disturbance 2 (1.30%), Tachycardia 4 (2.70%), Leg Pain 10 (6.80%), Back Pain 17 (11.70%), Neck Pain 5 (3.40%), Ulcers in mouth 3(2%), Tooth pain 1 (0.60%), Epigastric Pain 5 (3.40%), Hypotension 7 (4.80%), Swelling of knee 2 (1.30%), Facial puffiness 5 (3.40%), Weight gain 6 (4.10%), Blister Development 2 (1.30%).

CONCLUSION

Our study demonstrates that the COVISHIELD vaccine is highly effective against the novel coronavirus. The results of our study suggest that people who received both prime and booster doses have shown good effectiveness to vaccine without any severe adverse drug reactions. It is concluded that adverse effects which appear after the dose received are not very severe, can be relieved within two or three days. Overall, the safety of the COVISHIELD vaccine is much effective. Further investigations are required to study the long-term efficacy of the vaccine and long-term adverse effects after two doses of vaccine are to be evaluated.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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