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Comparative Study Of Indian Vaccines And Global Vaccines For Covid-19

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ABSTRACT

Background

The COVID-19 pandemic in India is a part of the worldwide pandemic of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).. In October 2021, the World Health Organization estimated 4.7 million excess deaths, both directly and indirectly related to COVID-19 to have taken place in India. [1] The first cases of COVID-19 in India were reported on 30 January 2020 in three towns of Kerala, among three Indian medical students who had returned from Wuhan, the epicentre of the pandemic. Lockdowns were announced in Kerala on 23 March, and in the rest of the country on 25 March. Infection rates started to drop in September. Daily cases peaked mid-September with over 90,000 cases reported per-day, dropping to below 15,000 in January 2021. A second wave beginning in March 2021 was much more devastating than the first, with shortages of vaccines, hospital beds, oxygen cylinders and other medical supplies in parts of the country. India began its vaccination programme on 16 January 2021 with AstraZeneca vaccine (Covishield) and the indigenous Covaxin. Later, Sputnik V and the Moderna vaccine was approved for emergency use too.[3] On 30 January 2022, India announced that it administered about 1.7 billion doses of vaccines and more than 720 million people were fully vaccinated. **Objective:** The main objectives of this paper are to provide awareness and to identify the research areas related to COVID-19. It may help improve the understanding of this disease and describe the psychological impacts of this pandemic and how these could change as the disease spreads. **Conclusion :** The real-world studies of vaccine effectiveness measure to which extent a certain vaccine has succeeded in preventing COVID-19 infection, symptoms, hospitalization and death for the vaccinated individuals in a large population under routine conditions that are less than ideal.

Keywords : PPE kit, SARS-CoV-2**,** Novel strain, Self-isolation, Pandemic, Herd immunity.

INTRODUCTION

Since the beginning of the corona virus disease 2019 (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the world has taken significant measures to cope with this disease, from increasing personal protection equipment (PPE) production and emphasizingthe importance of social distancing/masking to the Emergency Use Authorization (EUA) of remdesivir therapeutic antibodies and the applicationof the well-known corticosteroid dexamethasone.

However, the disease is still spreading in an unrelenting fashion and has caused widespread health, social, and economic disruption. Therefore, effective vaccines are urgently needed to end this pandemic and help society return to normalcy. Indeed, many COVID-19 candidate vaccines have been researched, developed, tested, and evaluated at an unprecedented speed. Asof the end of February 2021, several vaccines have been conditionally approved, and others are close to such approval. It is likely that many more still in clinical trials will come to market in the next few years.

Vaccination is considered one of the greatest medical achievements of moderncivilization. The eradication of smallpox is one of the best examples of how vaccination stopped a deadly disease and saved millions of lives.

1. WHAT IS COVID 19

COVID-19 is the disease caused by a new coronavirus called SARS-CoV-2. WHO first learned of this new virus on 31 December 2019, following a report of a cluster of cases of 'viral pneumonia' in Wuhan, People's Republic of China.

1.1 WHAT ARE THE SYMPTOMS OF COVID 19

The most common symptoms of COVID-19 areFever, Dry cough, Fatigue
Other symptoms that are less common and may affect some patients include:

Loss of taste or smell, Nasal congestion, Conjunctivitis (also known as redeyes) Sore throat, Headache, Muscle or joint pain, Different types of skin rash, Nausea or vomiting, Diarrhea, Chills or dizziness.

1.2 SYMPTOMS OF SEVERE COVID-19 DISEASE INCLUDE:

Shortness of breath, Loss of appetite, Confusion, Persistent pain or pressure in the chest, High temperature (above 38 °C). Other less common symptoms are Irritability, Confusion, Reduced consciousness (sometimes associated with seizures), Anxiety, Depression, Sleep disorders, more severe and rare neurological complications such as strokes, brain inflammation, delirium and nerve damage. People of all ages who experience fever and/or cough associated with difficulty breathing or shortness of breath, chest painor pressure, or loss of speech or movement should seek medical care immediately. If possible, call your health care provider, hotline or health facility first, so you can be directed to the right clinic.

2. COVID 19 PANDEMIC IN INDIA.

The COVID-19 pandemic in India is part of the worldwide pandemic of corona virus disease 2019 (COVID-19) caused by severe acute respiratory syndrome corona virus 2 (SARS-CoV-2). The first case of COVID-19 in India,which originated from China, was reported on 30 January 2020. India currently has the largest number of confirmed cases in Asia. As of 12 Jun 2021, India has the second-hi̅ghest n̄umber of confirmed cases in the world (after the United States) with 29.3 million reported cases of COVID-19 infection and the third-highest number of COVID-19 deaths (after the United States and Brazil) at 367,081 death.

Sr.No.	Date	No. of cases	No. of deaths
1	2021.06.03	28,441,986	337,989
2	2021.06.04	28,574,350	340,702
3	2021.06.05	28,694,879	344,082
4	2021.06.06	28,809,339	346,759
5	2021.06.07	28,909,975	349,186
6	2021.06.08	28,996,473	351,309
7	2021..06.09	29,089,069	353,528
8	2021.06.10	29,183,121	359,676
9	2021.06.11	29,274,823	363,079
10	2021.06.12	29,359,155	367,081

Table no. 1 : COVID-19 cases in INDIA

3. DRUGS USED IN COVID 19

3.1 REMDESIVIR

Remdesivir (Veklury) was the first drug approved by the FDA for treating theSARS-CoV-2 virus. It is indicated for treatment of COVID-19 disease in hospitalized adults and children aged 12 years and older who weigh at least 40 kg. The broad-spectrum antiviral is a nucleotide analog prodrug.

3.2 DEXAMETHASONE

Corticosteroids, such as dexamethasone, may help manage symptoms in people with COVID-19 by reducing inflammation. They also may reduce therisk of death in some people with severe symptoms.

A doctor may prescribe both steroids and antiviral in some cases.

As scientists continue to research the disease and potential treatments, more drugs may receive government approval. First however clinical trialsmust show that they are safe and effective.

3.3 HYDROXYCHOLOQUINE

It is not a safe option Early in the pandemic, the FDA gave approval to use the antimalarial drugs hydroxychloroquine and chloroquine as an emergency treatment for COVID-19 symptoms of a risk of "serious and potentially life threatening heart
rhythm problems" when using these drugs, and withdrew the approval inJune.

3.4 FAVIPIRAVIR

Glenmark Pharmaceuticals announced that it will introduce a 400 mg version of oral antiviral FabiFlu, for the treatment of mild to moderateCOVID-19 in India.

4. WHAT TYPES OF COVID-19 VACCINES ARE BEINGDEVELOPED? HOW WOULD THEY WORK

Scientists around the world are developing many potential vaccines for COVID-19. These vaccines are all designed to teach the body's immune system to safely recognize and block the virus that causes COVID-19.

Several different types of potential vaccines for COVID-19 are indevelopment, including:

4.1 INACTIVATED OR WEAKENED VIRUS VACCINES

They use a form of the virus that has been inactivated or weakened so it doesn't cause disease, but still generates an immune response.

4.2 PROTEIN-BASED VACCINES

They use harmless fragments of proteins or protein shells that mimic theCOVID-19 virus to safely generate an immune response.

4.3 VIRAL VECTOR VACCINES

They use a safe virus that cannot cause disease but serves as a platform toproduce corona virus proteins to generate an immune response.

4.4 RNA AND DNA VACCINES

A cutting-edge approach that uses genetically engineered RNA or DNA togenerate a protein that itself safely prompts an immune response.

Vaccines Platform	Developer/manufacturer	Vaccines	Clinical Stage	Route Of Administration
Live attenuated virus	Codogenix/serum instituteof India	COVI-VAC	Phase 1	IN (1-2)
Inactivated	Sinovac (China)	CoronaVac	Phase 4	IM (2)
	Wuhan Institute ofBiological Product/Sinopharm(China)	N.A.	Phase 3	IM (2)
	Beijing Institute OfBiological Product/Sinopharm(China)	BBIBP.CorV	Phase 3	IM (2)
	Bharat Biotech	Covaxin	Phase 3	IM (2)
	Institute Of Medical Biology (China)	N.A.	Phase 2	IM (1,2,3)
	Valneva,National Institute Of Health Research (UK)	VLA2001	Phase ½	IM (2)
	Erciyes University (Turkey)	ERUCOV-VAC	Phase 1	IM (2)
	Shifa Pharmed Industrial(Iran)	N.A.	Phase 1	IM (2)

Table No. 2 : Vaccines against COVID-19 in CLINICAL Trials.

5. VACCINES IN INDIA FOR COVID 19

5.1 COVAXIN

Covaxin is an inactivated vaccine which means that it is made up of killed corona viruses, making it safe to be injected into the body. Bharat Biotech, a24-year-old vaccine maker with a portfolio of 16 vaccines and exports to 123countries, used a sample of the corona virus, isolated by India's National Institute of Virology. When administered, immune cells can still recognize the dead virus, prompting the immune system to make antibodies against the pandemic virus. The two doses are given four weeks apart. The vaccine can be stored at 2C to 8C.The vaccine has an efficacy rate of 81%, preliminary data from its phase 3 trial shows. India's regulators gave the vaccine an emergency approval in January while the third phase of the trial was still underway, sparking scepticism and questions from experts. Bharat Biotech says it has a stockpile of 20 million doses of Covaxin, and is aiming to make 700 million doses out of its four facilities in two cities by the end of the year.

5.1.1 MECHANISM OF ACTION COVAXIN

The vaccine is used along with immune stimulants, commonly known asvaccine adjuvants (Alhydroxiquim-II), to improve immune response and longer-lasting immunity. The vaccine candidate is produced through the formulation of the inactivated virus with Kansas-based ViroVax's Alhydroxiquim-II adjuvant.

COVAXIN mainly contains 6µg of whole-virion inactivated SARS-CoV-2 antigen (Strain: NIV-2020-770), and the other inactive components such as250µg aluminum hydroxide gel, 15µg TLR 7 / 8 agonist (imidazoquinolinone), 2.5mg TM 2-phenoxyethanol, and phosphate buffer saline up to 0.5ml.

The vaccine requires no sub-zero storage and reconstitution requirementand available for use in multi-dose vials, stable at 2-8℃

5.1.2 SIDE EFFECT OF COVAXIN

Adverse events include fatigue, body aches, nausea, vomiting, and chills. Noserious side effects were reported. Some common ailments that can be expected after vaccination .

5.2 COVISHEILD

The Oxford-AstraZeneca vaccine is being manufactured locally by the Serum Institute of India, the world's largest vaccine manufacturer. It says , it is producing more than 60 million doses a month. The vaccine is made from a weakened version of a common cold virus (known as an adenovirus) from chimpanzees. It has been modified to look more like corona virus - although it can't cause illness. It is a recombinant, replication deficient chimpanzee adenovirus vector encoding (SARS CoV2 Spikes) glycoprotein. Follow in administration, the genetic material of part of corona virus is expressed whichstimulates an immune response. When the vaccine is injected into a patient,it prompts the immune system to start making antibodies and primes it to attack any corona virus infection.

The jab is administered in two doses given between four and 12 weeks apart. It can be safely stored at temperatures of 2C to 8C and can easily be delivered in existing health care settings such as doctors' surgeries.

The jab developed by Pfizer-BioNTech, which is currently being administered in several countries, must be stored at -70C and can only be moved a limited number of times - a particular challenge in India, where summer temperatures can reach 50C.

5.2.1 MECHANISM OF ACTION

It is a monovalent vaccine composed of a single recombinant, replication-deficient chimpanzee adenovirus (ChAdOx1) vector encoding the S glycoprotein of SARS-CoV-2. Following administration, the S glycoprotein of SARS-CoV-2 is expressed locally stimulating neutralizing antibody and cellular immune responses.

5.2.2 Side Effect

Following side effects or adverse reactions have been reported with COVISHIELD^{TM} vaccine.

Very common (may affect more than 1 in 10 people) - tenderness, pain, warmth, or itching where the injection is given, generally feeling unwell, feeling tired (fatigue), chills or feeling feverish, headache, feeling sick (nausea),joint pain or muscle ache

Common (may affect more than 1 in 10 people) - swelling or rednesswhere the injection is given, fever, being sick (vomiting) or diarrhea, pain in legs or arms, flu-like symptoms, such

as high temperature sore throat,Uncommon (may affect up to 1 in 100 people) – sleepiness or feeling dizzy, abdominal pain, enlarged lymph nodes, excessive sweating, itchy skin, rashor hives

Not known (the frequency cannot be determined from the available data) -severe allergic reaction (anaphylaxis), severe swelling of the lips, mouth, throat (which may cause difficulty in swallowing or breathing)

Rarest: Major blood clotting (venous and/or arterial thrombosis) in combination with low platelet count (thrombocytopenia) have been observedvery rarely (with a frequency less than 1 in 100,000 vaccinated individuals)

5.3 SPUTNIK V

The Sputnik V vaccine, developed by Gamaleya , National Research Institute of Epidemiology and Microbiology in Moscow, uses two different viruses that cause the common cold (adenovirus) in humans. The adenoviruses are weakened so they cannot replicate in humans and cannotcause disease. They are also modified so that the vaccine delivers a code formaking the corona virus spike protein. This aims to ensure that when the real virus tries to infect the body, it can mount an immune response in the form of antibodies.

Sputnik uses a different vector for each of the two shots in a course of vaccination. This provides immunity with a longer duration than vaccines using the same delivery mechanism for both shots, according to the Russian Direct Investment Fund (RDIF). The two shots are given 21 days apart.

Sputnik V is to be stored at -18°C in its liquid form. However, in its freeze- dried form, it can be stored at 2-8°C, in a conventional refrigerator without any need to invest in additional cold-chain infrastructure. Sputnik V is approved for use in over 55 countries with a total population of over 1.5 billion people, according to RDIF. It has proposed to price the vaccine at lessthan $10 per shot.

5.3.1 MECHANISM OF ACTION : Sputnik V uses a weakened virus to deliver small parts of a pathogen and stimulate an immune response. The Sputnik V (Gam-COVID-Vac) vaccine reduces the time taken for the actual development of immunity to SARS-CoV-2, the virus behind the COVID-19 pandemic.

5.3.2 Side Effect

In our study, fever, body/muscle pain, chills, fatigue, headache, and injection site pain were the most common SEs of Sputnik v, with the order of these symptoms varing between doses. Among them, headache, fatigue, and chills were also observed as the most frequent systemic SEs in a large-scale study conducted in the india. Injection site pain was reported as the most common SE, though only the first dose was considered. Furthermore, injection site pain, fatigue, headache, feverishness, and myalgia were the most common SEs in the Sputnik v clinical trial phase 2/3 .

Our findings are also consistent with similar studies , though the order varies, as injection site pain was more common following the second dose than the first one. This reactogenicity can be attributed to various factors related to the administrators, vaccines, and recipients that can not necessarily explain this difference between doses. Educating vaccine recipients, providing an appropriate environment for vaccination, and using suitable injection methods can reduce injection site pain . In contrast to previously reported Sputnik V-related cases , we did not find laboratory confirmation of coagulation disorders or deaths caused by this vaccine.

6. GLOBAL VACCINES FOR COVID 19

Details of the COVID-19 vaccines supported under Mission COVID Suraksha, which received Emergency Use Authorization (EUA), are given below:

1. ZyCoV-D- World's 1st and India's indigenously developed DNA Vaccine.Received EUA on 20th August, 2021 for use in 12 years and above age group; Then EUA on 26th April 2022 for 2-dose regimen;

2. CORBEVAX™-India's first protein subunit vaccine. (Received EUA on 29th December 2021 for use in >18 age group; subsequently on 22nd February, 2022 for use in 12-18 year age group; and on 26th April, 2022 for use in 5-12 years age group; included as heterologous "precaution dose" on 4th June, 2022);

3. GEMCOVAC™-19 - World's 1st and India's indigenously developed mRNA vaccine. (Received EUA on 28th June, 2022);

4. iNCOVACC-World's 1st and India's indigenously developed intranasal COVID-19 Vaccine(Received EUA on 6th September, 2022 for use in primary series for 18 years and above and on25th November, 2022 as homologous and heterologous booster).

6.1 RNA VACCINES

Examples :

a) Pfizer BioNTech COVID 19 vaccine

b) Moderna COVID 19 vaccine

c) CVnCoV RNA vaccine from CureVac

An RNA vaccine contains RNA which, when introduced into a tissue, acts asmessenger RNA (mRNA) to cause the cells to build the foreign protein and stimulate an adaptive immune response which teaches the body how to identify and destroy the corresponding pathogen or cancer cells. RNA vaccines often, but not always, use nucleoside-modified messenger RNA. The delivery of mRNA is achieved by a co-formulation of the molecule into lipid nanoparticles which protect the RNA strands and help their absorptioninto the cells

RNA vaccines were the first COVID-19 vaccines to be authorized in the United Kingdom, the United States and the European Union As of January2021, authorized vaccines of this type are the **Pfizer–BioNTech COVID-19vaccine** and the **Moderna COVID-19 vaccine**. As of February 2021, the **CVnCoV** RNA vaccine from **CureVac** is awaiting authorization in the EU. Severe allergic reactions are rare. In December 2020, 1,893,360 first dosesof Pfizer–BioNTech COVID-19 vaccine administration resulted in 175 casesof severe allergic reaction, of which 21 were **anaphylaxis**. For 4,041,396 Moderna COVID-19 vaccine dose administrations in December 2020 and January 2021, only ten cases of anaphylaxis were reported The **lipid nanoparticles** were most likely responsible for the allergic reactions.

6.2 ADENOVIRUS VECTOR VACCINES

Examples :

a) Oxford-AstraZeneca COVID-19 vaccine

b) Convidecia

c) Johnson & Johnson COVID-19 vaccine

These vaccines are examples of non-replicating viral vector vaccines, usingan adenovirus shell containing DNA that encodes a SARS-CoV-2 protein.
The viral vector-based vaccines against COVID-19 are non-replicating, meaning that they do not make new virus particles, but rather produce onlythe antigen which elicits a systemic immune response.

As of January 2021, authorized vaccines of this type are the Oxford–AstraZeneca COVID-19 vaccine, the Sputnik V COVID 19 vaccine, Convidecia, and the Johnson & Johnson COVID-19 vaccine.

Convidecia and the Johnson & Johnson COVID-19 vaccine. are both one- shot vaccines which offer less complicated logistics and can be stored underordinary refrigeration for several months.

The Sputnik V COVID 19 vaccine, uses Ad26 for the first dose, which is thesame as the Johnson & Johnson vaccine's only dose, and Ad5 for the second dose. Convidecia uses Aid for its only dose.

6.3 INACTIVATED VIRUS VACCINES

Examples

a) Chinese CoronaVac,
b) BBIBP-CorV
c) WIBP-CorV
d) CoviVac.
e) Valneva COVID-19 vaccine

Inactivated vaccines consist of virus particles that have been grown in culture and then are killed using a method such as heat or formaldehyde to lose disease producing capacity, while still stimulating an immune response.

As of January 2021, authorized vaccines of this type are the Chinese CoronaVac, BBIBP-CorV, and WIBP-CorV; the Indian Covaxin; and the Russian CoviVac. Vaccines in clinical trials include the Valneva COVID-19vaccine.

6.4 SUBUNIT VACCINES

f) peptide vaccine EpiVacCorona
g) RBD-Dimer.
h) Novavax
i) SOBERANA
j) Sanofi–GSK vaccine.

Subunit vaccines present one or more antigens without introducing wholepathogen particles. The antigens involved are often protein subunits, but can be any molecule that is a fragment of the pathogen.

As of April 2021, the two authorized vaccines of this type are the peptide vaccine EpiVacCorona and RBD-Dimer. Vaccines with pending authorizations include the Novavax COVID-19 vaccine, SOBERANA 02 (a conjugate vaccine), and the Sanofi–GSK vaccine. The V451 vaccine was previously in clinical trials, which were terminated because it was found that the vaccine may potentially cause incorrect results for subsequent HIVtesting.

6.5 OTHER TYPES

k) DNA plasmid vaccines
l) lentivirus vector vaccines

Additional types of vaccines that are in clinical trials include virus-like particle vaccines, multiple DNA plasmid vaccines at least two lentivirusvector vaccines, a conjugate vaccine, and a vesicular stomatitis virus displaying the SARS-CoV-2 spike protein.

Oral vaccines and intranasal vaccines are being developed and studied.

Scientists investigated whether existing vaccines for unrelated conditionscould prime the immune system and lessen the severity of COVID-19 infection. There is experimental evidence that the BCG vaccine for tuberculosis has non-specific effects on the immune system, but no evidence that this vaccine is effective against COVID-19.

CONCLUSION

7.1 EFFICACY

Vaccine efficacy is the risk of getting the disease by vaccinated participants in a controlled trial compared with the risk of getting the disease by unvaccinated participants. An efficacy of 0% means that the vaccine does not work (identical to placebo). An efficacy of 50% means that there are halfas many cases of infection as in unvaccinated individuals.

7.2 EFFECTIVENESS

The real-world studies of vaccine effectiveness measure to which extent a certain vaccine has succeeded in preventing COVID-19 infection, symptoms, hospitalization and death for the vaccinated individuals in a large population under routine conditions that are less than ideal.

- In Israel, among the 715,425 individuals vaccinated by the Moderna or Pfizer-BioNTech vaccines during the period 20 December 2020, to28 January 2021, it was observed for the period starting seven days after the second shot, that only 317 people (0.04%) became sick with mild/moderate Covid-19 symptoms and only 16 people (0.002%) were hospitalized.
- The Pfizer-BioNTech and Moderna Covid-19 vaccines provide highly effective protection, according to a report from the US Centers for Disease Control and Prevention (CDC). Under real-world conditions,mRNA vaccine effectiveness of full immunization (≥14 days after second dose) was 90% against SARS-CoV-2 infections regardless of symptom status; vaccine effectiveness of partial immunization (≥14 days after first dose

but before second dose) was 80%.

- 15,121 health care workers from 104 hospitals in England, that all had tested negative for COVID-19 antibodies prior of the study, werefollowed by RT-PCR tests twice a week from 7 December 2020 to
  5 February 2021, during a time when lineage B.1.1.7 was in circulation as the dominant variant. The study compared the positive results for the 90.7% vaccinated share of their cohort with the 9.3% unvaccinated share, and found that the Pfizer-BioNTech vaccine reduced all infections (including asymptomatic), by 72% (58-86%) three weeks after the first dose and 86% (76-97%) one week after the second dose.
- A study of the general population in Israel conducted from 17 January to 6 March 2021, during a time when lineage B.1.1.7 was incirculation as the dominant variant; found that the Pfizer vaccine reduced asymptomatic COVID-19 infections by 94% and symptomatic COVID-19 infections by 97%.
- A study, among pre-surgical patients across the Mayo Clinic systemin the United States, showed that mRNA vaccines were 80% protective against asymptomatic infections.
- A study in England found that a single dose of the Oxford– AstraZeneca COVID-19 vaccine is about 73% (27–90%) effective inpeople aged 70 and older.

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