Review article
Covid vaccine dilemma curbing the herd immunity in India- Jab or no jab?

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ABSTRACT

After the devastating second wave of COVID-19, with the rapid increase in the number of new cases in many states of India marking the beginning of a probable third wave of COVID-19, our best bet is taking a jab to protect against COVID-19. Currently, licensed vaccines are found to be reasonably safe and effective. The second wave of COVID-19 was devastating, but it’s a silver lining to note that most of the individuals who had taken the jab recovered with mild infections, and the hospitalization rates among jabbed individuals were meager. Various rumours related to the efficacy, safety, content, and side effects of the vaccine in India had caused a plunge in the vaccine acceptance rate leading to hesitancy and carelessness among the Indian population. This is a critical time for facts, not fear or rumors. This review provides an insight into the myths, pros and cons, and efficacy of the available vaccines.

Keywords: COVID-19; covishield; covaxin; vaccination; India.

INTRODUCTION

The Coronavirus disease is an invisible enemy, a lethal single-stranded RNA virus belonging to the family coronaviridae, mimicking severe acute respiratory syndrome. This disease produces a wide range of symptoms from the common cold, diarrhea to fatal illnesses. It first originated in the city of Wuhan in China in 2019, hence coined as covid-19, after which it has rapidly spread to various countries worldwide, rendering it a pandemic (1). This novel virus name was replaced with “SARS-CoV-2” due to the respiratory symptom depicted.

The outbreak of coronavirus disease has played a devastating role, infecting over 206 million people worldwide as of August 13 th, 2021. India, the United States of America (USA), and Brazil (2). The second wave has gripped India, with more than 27 million cases of COVID-19 and more than 300,000 deaths (3).

India has overtaken the USA in this wave and is the hardest hit country globally regarding socioeconomics burden. The government reported an unprecedented surge of 352,991 new infections cases on 25 April 2021. Daily global cases have surpassed 899,755 in a week, breaking a record set in January (4).

In May 2020, 95% of the total COVID-19 positive cases were found in urban spaces. 40% of the total cases in the country were found in the four densely populated cities in India; Delhi, Mumbai, Chennai, and Kolkata. This further spread to rural areas in the second wave. One out of six Indian resides in an urban slum that are situated in close proximity with no proper ventilation. Restraining the spread was an arduous task and nearly impossible in this living condition (5). Precise treatment for this deadly disease is still in progress, and nationwide all countries have diverted their efforts towards curbing this detrimental health hazard. The silver lining was observed around the world when a vaccine was secured, and it relieved the emotional, mental, physical, and economic baggage faced worldwide. India started the largest vaccination drive on January 16 th, 2021, with two vaccines available, Covishield (Serum Institute, Pune, India) and Covaxin (Bharat Biotech, Hyderabad, India) to develop herd immunity. Both are administered in two doses intramuscularly (6). Even though safe and effective vaccines were issued, there was a surge in daily cases in India.

Moreover, vaccination programs, especially in India, have faced significant obstacles. Sporadically 10% of the target population in the country was vaccinated by the end of March, and in the stipulated period, end of June, the remaining 90% needed to be covered. Varied rumours related to the efficacy, safety, content, and side effects of the vaccine in India had caused a plunge in the vaccine acceptance rate leading to hesitancy and carelessness (7). Thus, interfering in curbing the catastrophic spread of this disease.

To identify the scope of this problem, this non-systematic review aimed to assess the acceptance rates for COVID-19 vaccines in different cities in India and provide insight into the myths, pros and cons, and efficacy of the available vaccines. Thus, eradicating the potential for fallacy which lies behind these vaccines.

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Brief literature search
This narrative review highlights a brief non-systematic methodology to include the selected articles for discussion. A systematic search of Scopus, Web of science, Pubmed, WHO global research on COVID-19 and the clinical trials register "https://clinicaltrials.gov/" data bases was done from data inception to July 2021 using the following MeSH terms (Coronavirus disease 2019 or COVID 19), SARS- CoV-2, COVID -19 vaccination in India, vaccines, Covishield and Covaxin. Only published articles in English were included.

DISCUSSION

I. Vaccination in India

Vaccines available
There are several vaccines now administered in India. However, Covishield and Covaxin are the two abundantly administered. Apart from these, there are plenty in the market; some local pharmaceutical and biotech companies have signed collaborative agreements with foreign-based vaccine developers.

- A non-replicating chimpanzee adenovirus vaccine vector (ChAdOx1), Covishield developed by Serum Institute of India (SII), Pune, India (in alliance with the university of Oxford, UK, and AstraZeneca a British multinational pharmaceutical company).
- Covaxin an inactivated virus vaccine (BBV152), targeting SARS-CoV-2 developed by Bharat Biotech Ltd, Hyderabad, India (in collaboration with the National Institute of Virology of ICMR, India).
- Zydus Cadila vaccine (ZyCoV-D) - a plasmid DNA vaccine manufactured by Cadila Healthcare (Zydus Cadila), Ahmedabad, India (supported by the department of Biotechnology, Government of India).
- Corbevax a recombinant RBD protein -based vaccine, with adjuvant CpG 1018 developed by Biological E.Limited, Hyderabad, India.
- An unnamed vaccine developed by Dynavax technologies Corporation and Baylor college of Medicine, USA.
- Sputnik V- an inactivated human adenovirus Ad5 and Ad 26 with spike protein inserts manufactured by Dr. Reddy's Laboratories, Hyderabad, India (vaccine developed by Gamaleya National Research Institute of Epidemiology and Microbiology, Moscow, Russia).
- A novel mRNA -based vaccine candidate (HDT-301) developed by Gennova Biopharmaceuticals Ltd, Pune, India (in collaboration with HDT Biotech Corporation, USA) (8).

II. Vaccine drive phases
Accordingly, these vaccines were allocated in phases by the National Expert Group on Vaccine Administration for COVID-19 (NEGVC). These vaccines were first offered to healthcare workers, frontline workers, followed by senior citizens above 60 years of age. By 14th April, more than 111 million people had been vaccinated in the country. However, anticipating vaccine shortage, the government halted the export of Oxford–AstraZeneca vaccine, also known as Covishield (9). India claimed to vaccinate over 300 million of its population, therefore speculated to procure 600 million doses. The next phase vaccinated individuals above 45 years with/without co-morbidities. The following phase vaccinated individuals above 18 years. However, below 18 years are still facing the brunt and eagerly awaiting the green signal.

III. Current vaccination scenario in India
As of 14th August 2021, the ministry of health and family welfare reported that India has vaccinated 536188903 of its population amidst a total of 1.3 billion, which is not even half of its population. The second-largest populated country in the world is facing a jolt with vaccination acceptance. State-wise cumulative vaccination rate is shown in table 1 (10). The target of vaccinating 90% of the population by the end of June was not achieved.

The total population in India and the status of the population vaccinated as of August 13th 2021 are as shown in table 2 (11). The majority of the states have jabbed their population except for Uttar Pradesh, Maharashtra, Bihar, Jharkhand, Madhya Pradesh, Meghalaya, Nagaland, Odisha, Punjab, Rajasthan, Tamil Nadu, Telangana, Chhattisgarh, West Bengal, and Assam. These states have jabbed less than 50% of their population. The preponderance of population among these states and their perplexed attitude are the drawback of their vaccination campaign.

A number of states have been successful in their vaccination campaign and have jabbed the bulk of their population such as Goa, Sikkim, Kerala, Andaman & Nicobar, Tripura, Delhi Daman and Diu, Lakshadweep, and Ladakh. Vaccination in kids and below 18 years is still awaited, and clinical trials are in progress in these age groups. Parents are skeptical and bewildered.
**Table 1:** Cumulative coverage report of COVID-19 vaccination

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<tr>
<th>S. No.</th>
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<th>Beneficiaries Vaccinated</th>
<th>Beneficiaries Vaccinated</th>
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<td>1st Dose</td>
<td>2nd Dose</td>
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<td>41,68,46,115</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>(50,31,693 in last 24 Hours)</td>
<td>(13,49,244 in last 24 Hours)</td>
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<th>S. No.</th>
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<td>1,11,44,693</td>
<td>23,86,260</td>
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<td>5</td>
<td>Bihar</td>
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<td>38</td>
<td>Miscellaneous</td>
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DOI: https://doi.org/10.51248/v41i4.975
The efficacy rate of vaccines varies, with 81% efficacy in Covaxin and 70% in Covishield, respectively (14). A study proclaimed that administration of both doses of the Covaxin vaccine regimen significantly boosted the IgG titre, thus neutralizing efficacy against both the variants compared to that seen with natural SARS-CoV-2 infection (15). Several SARS-CoV-2 variants B.1.1.7, B.1.351, and B.1.1.28.1 have been reported in India in 2021, with another emerging variant causing a recent surge in Maharashtra B.1.617 in June 2021, as per the ICMR data. This new variant is known to have a high transmissibility with an increase in hospitalization (16). It is noteworthy that this variant has fared poorly against vaccines (17). The B.1.617 variant was isolated in patients hospitalized in the intensive care unit (ICU). Its clinical presentation is characterized by higher pneumonia rates, respiratory failure, and elevated inflammatory markers compared to the Delta variant. There is a strong emphasis on the role of vaccination in curbing the spread of this variant (18). Understanding the characteristics and impact of these variants is crucial for guiding vaccination strategies and public health measures.

IV. Efficacy of vaccines

COVID-19 vaccines do not offer 100% protection, and breakthrough infection has been observed in abundance. However, reports and studies suggest less virulence in these vaccinated individuals. Indian Council of Medical Research (ICMR) suggested recurrence of infection in 0.13% and 0.07% following both doses of Covishield and Covaxin (12). India reported 0.06% of vaccinated Health Care Workers (HCW) /patients were hospitalized in an observational study conducted in a renowned hospital (13). Post-vaccination majority of the breakthrough infections were asymptomatic, with one fatality and two hospitalizations.

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was observed. This provides clear evidence that immunization does reduce hospital admissions and death (18). The safety, immunogenicity, and efficacy data of Covishield administered on 23,745 participants over 18 years outside India showed 70.42% vaccine efficacy (19). Fully vaccinated individuals had a lower incidence of SARS-CoV-2 infections than partially vaccinated and non-vaccinated individuals. The cumulative vaccine efficiency was determined to be 88.6% in fully vaccinated individual and 44.1% in partially vaccinated individuals (20). Despite these encouraging findings on vaccine effectiveness, few significant severe Adverse Events Following Immunization (AEFI) have been documented in partially and fully vaccinated individuals. BellsPalsy, Anaphylaxis, Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), pericarditis, myocarditis and rarely deaths have been reported (21, 22).

Recently a new-fangled experiment is in progress with the mixing of jab and is found to be more potent than homologous jab either by Covaxin or Covishield. Eighteen individuals received Covishield as the first jab and Covaxin as the second, and the safety and immunogenicity were effectively compared with 40 receiving the same jabs. The heterologous vaccine safety was determined by decreased adverse effects. Antibody titers and levels of IgG antibodies were always better in heterologous group to Alpha, Beta and Delta variant (23).

V. Reasons for hesitancy/ Low vaccination rate in India

- Vaccine development

The biggest obstacle across the globe initially related to vaccination stem is that the vaccines have been developed at a rapid pace as vaccines usually take years to develop. Methodically clinical trials and efficacy of these vaccines are monitored meticulously and take a very long duration for the vaccine to be introduced in the market. Moreover, the mechanism, storage, and cold chain of these vaccines in India is an arduous task and tedious work. However, this procedure and mechanism is almost entirely a mystery to the general population (24, 25).

- Vaccine dose interval/ vaccine efficacy

The second dose of covid vaccine, especially Covishield was initially given at an interval of 4 weeks to all the health care workers, frontline workers, and senior citizens. However, this interval got prolonged to 6 weeks, and then the government of India announced the gap to be prolonged to 12 weeks to vaccinate maximum people with the first dose. Some data from global trials of Covishield suggests that extending the duration between doses to 12 weeks increased its efficacy much more (22). Recurrent life-threatening conditions dropped significantly after 28 days of the second dose. Interim data from the studies in USA, Chile and Peru indicated that the vaccine had 79% effectiveness even when the second dosage was administered four weeks after the first dose (26).

In phase 3 clinical trials in the UK, Brazil, and South Africa, the efficacy of AZD1222 was around 54.9 percent when the second dose was given less than six weeks after the first dose. The efficacy increased to 59.9 percent when the second dose was administered 6-8 weeks after the first dose, and to 63.7 percent when administered 9-11 weeks after the first dose and 82.4% when the dosing interval stretched to 12 weeks or more. Covishield vaccine efficacy increased to 81.3% in > 12 weeks dose interval and 51.1% in short duration. Further claiming that antibodies start fading at 90 days (27). Astrazeneca vaccine efficacy and the various interval between doses is shown in Fig.1 (28).
Government mismanagement
The shortage of vaccine availability was speculated to be one of the reasons for increasing the interval. However, the government of India claimed to have no shortage, as announced by Dr. Harshvardhan. However as per, Dr. N K Arora of NTAGI, one of the groups that looked at present issue, declared that there was "no good scientific evidence" to promote a recommendation to extend the interval beyond eight weeks, especially given that India does not have a vaccine shortage” (29). He also believed that this recommendation was for countries and societies where there is a deficiency of vaccines. This unclear decision by the government of India based on their flexibility has triggered a negative notion related to the vaccine administration. The central government's unsynchronised allocation of the vaccine to various states also created a misconception among the population not ruled by the central party (30).

Reinfection
Another major obstacle and hesitance in administering the vaccine among the general population of India was the recurrence of infection in several health care workers and frontline workers even when they were fully vaccinated with both doses. This haunted the minds of the public about the vaccines’ competence. A similar reason for hesitation in 82.3% of medical students was collected coupled with the real concern regarding adverse events noticed from the vaccine's possible 'long term' effect. This apprehension was conjoint with the vaccines not been tested vigorously to determine all possible adverse events (31).

Vaccination cost
High cost of the vaccine, which is not favourable to the low-income group of people. This problem was resolved by providing vaccines in government hospitals free of cost. However, private sectors/ hospitals charged a minimum of Rs 250/-. A study done in West Bengal revealed that 40% of their subjects wanted a cheap vaccine, and 58% preferred an Indian vaccine (32).

Vaccination centres
In government centres the wait was long, approximately 10-12h, and was overcrowded. A working-class or a daily wage labourer was in a dilemma regarding the above-mentioned reason. However, the scare of acquiring the infection in these sectors made the public psychologically panic and avoid the vaccine administration. In both places, minimum vaccines were available daily, and people returned home empty-handed after visiting 2–3 times, which lead to hesitancy.

Adverse events after vaccination
Due to multiple factors other than the vaccines themselves, minimum adverse events, allergies, anaphylactic reactions, or some other life-threatening events occurred post-vaccination. But even rare events, like the post-vaccination clotting incidents in Europe, were enough to create massive doubt in people's minds (33).

Religion/Rumours related to the make of vaccine
Some religious groups opposed the vaccine based on rumours. Muslims and Jews aborted or declined the vaccination due to fictitious claims that vaccines contain infertility agents or spread the human immunodeficiency virus (HIV). Vaccine mutating the DNA and erectile dysfunction in males was the paramount concern in the population. Rumours related to COVID-19 vaccine reagents flawed the vaccination strategy among Christians and Buddhists, claiming that the COVID-19 vaccines were being produced with cells from aborted foetuses. Nevertheless, rumours also claimed vaccine production with genes from monkeys and pigs (25). A déjà vu was experienced earlier, and rubella and measles vaccines were boycotted due to similar beliefs, and the world had to face the brunt (34, 35). The aluminium present in these vaccines is claimed to cause Alzheimer's disease. A pharma gimmick was another conspiracy for the hesitancy. Misbelief in people regarding these rumours has led to a decline in immunization.

VI. Truth behind Covid Vaccines
In India, 700 severe and severe adverse events were reported from across the country over the unusual type of blood clots after receiving the AstraZeneca-Oxford University vaccine. This was rare, and the probability was 0.0001%, with the majority complaining of fever, myalgia, injection site pain, headache, and joint pain after the first dose (36, 37). Both vaccines, Covishield and Covaxin elicited a good immune response in health care workers across India after two doses of vaccination despite the fact that seropositivity rates and the median anti-spike antibody titer were significantly higher in Covishield (38). Protective levels of anti-SARS CoV-2 Ig G antibodies were in the majority after 14 days of the second dose (39).

The in-hospital mortality rate in a hospital in eastern India revealed that 60% of unvaccinated people succumbed to death, and 7.5 percent of those who received a double dose of Covishield died. However, 27.5 percent of those who received a single dose of Covishield died, and 5% died after receiving a single dose of Covaxin. The disease had comorbid conditions like diabetes mellitus, cardiovascular diseases, and malignancies in association with moderate to severe COVID-19. However, the cause of death was unknown, and reports further revealed that none reported infection after receiving a second dose of Covaxin (40). These findings suggest that the probability of severe adverse events or death due to
covid after vaccination was rare and negligible for a population so vast. Covishield vaccine contains L-Histidine, L-Histidine hydrochloride monohydrate, Magnesium chloride hexahydrate, Polysorbate 80, Sucrose, Ethanol, Disodium edetate dihydrate (EDTA), Sodium chloride, Water for injection and thus is benign and the rumours related to its contents are unjustified.

6µg of whole -vion inactivated SARS-CoV-2 antigen (Strain: NIV-2020-770), and the other inactive components such as 250µg aluminium hydroxide gel, 15µg TLR 7 / 8 agonist (imidazoquinolinone), 2.5mg TM 2-phenoxyethanol, and phosphate buffer saline up to 0.5ml is present in Covaxin. WHO has so far validated only six vaccines globally, the Johnson, the Pfizer vaccine, Sputnik V, Sinopharm-BIBP, Moderna, and two AstraZeneca vaccines for emergency use (41). The efficacy and safety of these vaccines were mentioned and discussed in detail earlier (26-28). The government of India has procured Moderna vaccine Pfizer bio Ntee, Sputnik V in order to speed up the vaccine drive. The mRNA vaccine has been reported to have an efficacy of 95% (Pfizer), whereas Moderna represented 94% efficacy, and these are currently in vogue in several countries (42). Natural immunity by COVID-19 may not last long, and evidence suggests reinfection. Therefore, vaccination is necessary for boosting immunity (43). There is also no difference in the doses, schedule, or platform. However, the vaccine is given to such subjects after 90 days. These suggest the rumours about the contents of the vaccine as fabricated.

All development programs in this short period aimed at synthesizing S-protein neutralizing antibodies in the bodies of vaccinated COVID-19 individuals. Researchers identified the presence of restricted or zero cross-neutralization in serum of both SARS-CoV and SARS-CoV-2. Thus, indicating that successful recovery from one disease is not guaranteed and can develop an infectious disease in the future. Therefore, these vaccines aim to either incite or weaken viruses’ live -conditions. A vaccine that provides 100% protection and eradicates corona completely is not developed and scientists around the globe are aiming to develop such vaccines shortly.

CONCLUSION

Indian population is still in a dilemma regarding covid 19 vaccination. Fewer than half of the Indian population are vaccinated six months down the lane, as of August 13th 2021. Uttar Pradesh, Maharashtra, Bihar, Jharkhand, Madhya Pradesh, Meghalaya, Nagaland, Odisha, Punjab, Rajasthan, Tamil Nadu, Telangana, Chhattisgarh, West Bengal, and Assam have vaccinated less than half of their population due to an apprehension related to vaccines. This review concludes that all the current covid vaccines face paradox as they are safe and efficient but abolishes 100% protection. Pfizer provides 95% and Moderna 94% with higher rates of side effects. However, Indian vaccines have lower efficacy rates with 81% in Covaxin and 70% efficacy in Covishield with more potency at 12 weeks intervals between doses. Thus, with these findings, we conjectured that in India, Covaxin is a potent vaccine to shield against the mutant variants of covid 19 and is the only way to develop herd immunity amongst the Indian population.

Data Availability

Data for the study is taken from the Ministry of Health and Family Welfare, Government of India site: https://www.mohfw.gov.in/.

CONFLICTS OF INTEREST

The authors declare that they do not have any conflicts of interest.

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