

Adverse Effects Of Covishield and Covaxin Post Vaccination for Sars-Cov-2- A Comprehensive Review

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ABSTRACT: The rising cases of people succumbing to the deadly virus put enormous pressure on the healthcare to ameliorate the situation with better treatment. Covishield and Covaxin are the two vaccines with two dosage regimen approved in India for immunization of the masses. As the vaccination process is in progress, the side effects due to these vaccines are being recorded and reported. The current trend depicts the Covid-19 vaccine Covaxin and Covishield used in India side effects are similar to normal viral vaccines and similar to those earlier warned about during the clinical trials. These so far are easily manageable.

I. INTRODUCTION

A vaccine activates the immune system to fight the disease and stop its communicability to provide herd immunity. The first case of Covid-19 was reported in Wuhan, China in 2019 and soon snowballed in the rest of the world. Till May 2021, India has reported a total of 28175044 cases with 331895 confirmed deaths. 27 deaths have been reported by the India's ministry of Health and

Family welfare but none of these are associated to Covid-19 vaccine. (1) About 4.33 cr people have been fully vaccinated that accounts to 3.2% of total population. (13)

AZD1222 COVID-19 vaccine developed by AstraZeneca and the Oxford University vaccine group was given approval in India on 2nd January 2021. The vaccine is a joint venture of AstraZeneca and Serum Institute of India, marketed under the name Covishield. (4) It is a viral vector vaccine which contains an inactive form of adenovirus that activates the immune system by forming coronavirus spike proteins as shown in figure 1. (1)

The joint efforts of Bharat's Biotech and ICMR Indian Council of Medical Research and its National Institute of Virology led to the development of India's endogenous vaccine-Covaxin. Covaxin is an inactivated pathogen vaccine which contains ineffective Covid-19 viral particle, modified in a way that makes it incapable of replication and disease transmission as shown in Figure 1. The virus with diminished activity expresses the antigenic proteins to lymphocytes. (12)

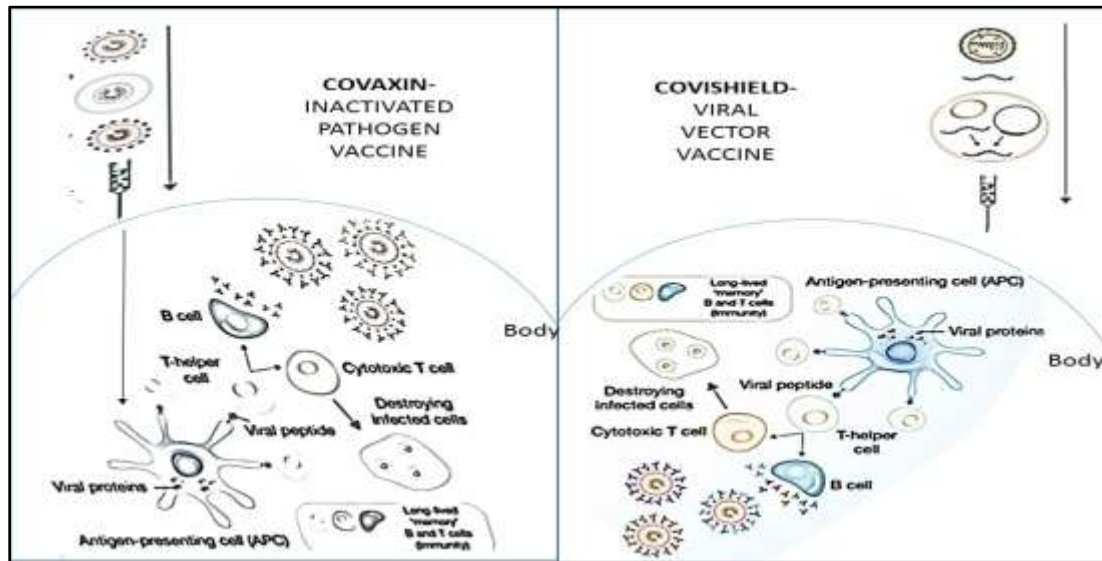


FIGURE 1: THE DEVELOPMENT AND MECHANISM OF ACTION OF COVISHIELD AND COVAXIN VACCINE.

Since the development of the vaccine in a short span of time was a herculean task, any adverse effects experienced should be noted to identify as well as rectify the pitfalls of the vaccine development.

COVISHIELD SIDE EFFECTS

The most common side effects seen in people after getting Covishield jab are-

- Systemic side effects occur within 24 hours and last for about 1-2 days (3) and include Fever with chills, headache, fatigue, nausea and vomiting(1).
- Local effects occur on the day of vaccination upto a mean of 1.2 days (3)-pain at the site of injection, swelling, tenderness and stiffness in the arm.(10)
- Very rare side effects as confirmed by the EMA's Pharmacovigilance Risk Assessment Committee – unusual blood clots with low blood platelet level.(7)
- The mass immunization in Nepal was initiated in January 2021 after receiving 10 million doses of Covishield.
- The following observations were made -
 - a) After 4 hours of vaccination- irritability in mood.
 - b) After 6 hours of vaccination- uneasiness, tenderness at injection spot, bodypain/feverish.
 - c) After 12 hours- fever with chills that can be cured with anti-pyretic NSAID- paracetamol. (2)

Adverse effects noted in the phase 3 clinical trial of the AstraZeneca vaccine- Systemic side effects were 27% more common than the local side effects after the first dose. The systemic side effects were more common in people of 50 years of age or younger.Both the systemic and local side effects were more frequent in people of 50 years of age or younger.Women reported more occurrences of these undesirable effects.Other side-effects included allergic skin reactions such as skin burning, rashes, and red welts on the lips and face. (3)

The incidents of hemorrhage, thromboembolism, and thrombocytopenia created a hysteria among who are patients on CVD and coagulation medication. The listed side effects were more common in the younger adults.(7)

26 events of thromboembolic after the AstraZeneca vaccine shot were reported that is equal to about 0.61 per million vaccine doses, compared with 10 and 4 per million doses in Germany and Britain, respectively.(6)

However, an unbroken relationship between the blood clots and the vaccine jab was assured in March month 2021 by the Medicine and Healthcare Regulatory Authority, UK. MHRA and EMA advised the population that the benefits of the vaccine are pragmatic and have an edge over the

side effects and people should continue get vaccinated.(5)

The fact sheet of Covishield includes rare events of demyelinating disorders (affecting the myelin sheath of brain) but with no evidence of direct connection with the vaccine side effects.(14)

COVAXIN SIDE EFFECTS

Side effects with the COVID-19 vaccine (COVAXIN) include:

- Local side effects-Injection site pain / Swelling / Redness / Itching (10)
- Other local side effects include-Stiffness in the upper arm, pain in the injection arm.(8)
- Systemic side effects- Headache, Fever, Malaise/body ache, nausea,dizziness,and sweating,cold,cough.
- A severe allergic reaction may very rarely occur after getting a dose of COVAXIN.(8)

- Signs of severe allergic reactions- Shortness of breath, swollen face or throat, increased heartbeat, weakness and lethargy. (10)

The following data was collected during the clinical trials - 5% headache; 3% fatigue, 3% fever, 2% nausea and 2% vomiting. (11)

Covaxin has not reported any blood clotting or thrombus formation side effects. (6)

A survey of renowned Indian doctors was conducted to estimate the side effects post Covaxin jab. Some of recorded a little but bearable soreness in her arms while most of doctors reported zero side effects and requested the public to get vaccinated soon. (18)

To safeguard the public health and avoid occurrence of major side effects it is advised that those suffering from bleeding disorders, immunodeficient, using blood thinners, pregnant, breastfeeding, or with a history of allergic reactions to any of the vaccine ingredients are should not take the vaccine right now. (15)

**TABLE 1: THE SIDE EFFECT OF COVISHIELD AND COVAXIN
 SIDE EFFECT OF VACCINE**

COVISHIELD VACCINE	COVAXIN VACCINE
Pain, redness, tenderness, swelling at injection site	Swelling, pain, redness at injection site
Fatigue , dizziness, abdominal pain	Stiffness in upper arm
Chill, fever, headache, Joint pain or muscle ache	Itching at injection site
Nausea, vomiting	Body ache, fever, headache
Lump at injection site	Malaise, weakness, rashes
Enlarged lymph nodes	Nausea, vomiting
Flu- like symptoms i.e.sore throat, runny nose, cough and high temperature	Weakness in injection arm
Rashes or itchy skin	

**TABLE 2: THE PERSON WHO CAN'T RECEIVE COVISHIELD AND COVAXIN
 PERSON WHO CAN'T RECEIVE VACCINE**

COVISHIELD VACCINE	COVAXIN VACCINE
HAVING SERIOUS ALLERGY IN HISTORY	HISTORY OF ANY ALLERGIES
ALLERGIC REACTION WITH THE INGREDIENT OF VACCINE	HAVING FEVER
	WOMEN WHO ARE PREGNANT AND BREASTFEEDING
	INDIVIDUALS ARE ON BLOOD THINNER
	INDIVIDUAL ARE IMMUNE-COMPROMISED
	ANY SERIOUS HEALTH ISSUES

II. RESULTS

Most of the side effects of Covishield and Covaxinare mild and curable under doctor's surveillance. The majority of the side effects are anticipated and familiar. These are occurring within two-three days post vaccination.

The individuals who experience any severe symptoms – such as shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurological symptoms, such as severe and persistent headaches or blurred vision, tiny blood spots under the skin beyond the site of the injection - from around four to 20 days following vaccination, should seek urgent medical attention.

III. CONCLUSION

The country is facing a tough time in defeating the Covid-19 pandemic virus. The only solution available at such a hard time is getting vaccinated to combat the further transmission of disease. Since the side effects are controllable, the government and health organizations advice the masses to get vaccinated. A remarkable decrease (39% decline) in the cases has been noted 12-21 days after the first dose of the vaccine. It is highly recommended as per the government guidelines that those suffering from severe side effects after the first dose should avoid taking the second jab.

A more detailed study and remarks on the adverse effects can be made once a larger sector of the Indian population gets vaccinated which till date accounts only to 3.2% of the total population.

REFERENCES

- [1]. Ariana Rimmel, COVID vaccines and safety: what the research says: *Nature* **590**, 538-540 (2021).
- [2]. Ranjit Sah, Sunil Shrestha, Rachana Mehta, Sohan Kumar Sah, Ali A. Rabaan, Kuldeep Dhama, Alfonso J. Rodriguez-Morales: AZD1222 (Covishield) vaccination for COVID-19: Experiences, challenges, and solutions in Nepal; *Travel Med Infect Dis.* 2021 March-April; 40: 101989.
- [3]. Cristina Menni, Kerstin Klaser, Anna May, Lorenzo Polidori, Joan Capdevila, Panayiotis Louca; Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID Symptom Study app in the UK: a prospective observational study; *Published: April 27, 2021.*
- [4]. Shivaji Kashte, Arvind Gulbake, Saadiq F. El-Amin III & Ashim Gupta; COVID-19 vaccines: rapid development, implications, challenges and future prospects; *Published: 07 March 2021; Human Cell* volume 34, pages 711–733 (2021).
- [5]. Hamid A. Merchant; CoViD vaccines and thrombotic events: EMA issued warning to patients and healthcare professionals; *Published: 24 March 2021; Journal of Pharmaceutical Policy and Practice* volume 14, 32 (2021).

- [6]. Bleeding and clotting with AstraZeneca's COVID-19 vaccine; Published 29 May 2021. Reactions Weekly 1857, 1 (2021).
- [7]. AstraZeneca COVID-19 vaccine: thrombosis with thrombocytopenia. , Published 17 April 2021; Reactions Weekly 1851, 1–2 (2021).
- [8]. 8.Fact sheet for vaccine recipients and caregivers-Restricted Use In Emergency Situation Of Covid-19 Sars-Cov-2 Vaccine By Bharat Biotech; Published by Bharat Biotech International Limited, Shamripat, Hyderabad, Telangana
- [9]. The current COVID-19 situation, World Health Organization, Latest update: 2 June 2021.
- [10]. Ministry of Health and Family welfare; Government of India, https://www.mohfw.gov.in/covid_vaccination/vaccination/common-side-effects-aeft.html
- [11]. Rimple Jeet Kaur, Siddhartha Dutta, Pankaj Bhardwaj, Jaykaran Charan, Sameer Dhingra, Prasenjit Mitra, Kavita Singh, Dharmveer Yadav, Praveen Sharma, Sanjeev Misra; Adverse Events Reported From COVID-19 Vaccine Trials: A Systematic Review; 3 March 2021; Ind J Clin Biochem.
- [12]. Nikolaos C. Kyriakidis, Andrés López-Cortés,, Eduardo Vásconez González, Alejandra Barreto Grimaldos and Esteban Ortiz Prado; SARS-CoV-2 vaccines strategies: a comprehensive review of phase 3 candidates; Nature's reprints.
- [13]. Statistics and research, Coronavirus, Covid-19 Vaccination, Our World in Data, updated on 1st June, 2021
- [14]. What to Expect Post Vaccination? How to Deal with Adverse Effects? The Quint, Published on 5th March 2021.
- [15]. DNA Explainer: Difference between Covishield, Covaxin, Sputnik V and possible side effects, Shampa Sen; DNA Web Desk, Updated: May 14, 2021.
- [16]. One in four people experience mild side effects from Covishield vaccine: Lancet study; NEW DELHI, APRIL 28, 2021.
- [17]. Interim statement of the COVID-19 subcommittee of the WHO Global Advisory Committee on Vaccine Safety on AstraZeneca COVID-19 vaccine; 7 April 2021.
- [18]. Nolan Pinto, Milan Sharma, Mausami Singh, Mustafa Shaikh, Abhishek Mishra, Kamlesh Sutar; Covid-19 vaccine side effects: What doctors who took the shot said, Indian Today; Published on- January 20, 2021.