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A COMPREHENSIVE REVIEW ON NON-THERAPEUTIC EFFECT AND SAFETY OF COVID 19 VACCINES

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ABSTRACT

COVID-19 continues to pose a significant threat to global health, necessitating widespread vaccination to curb its spread. This review examines the side effects (SEs) and adverse clinical cases associated with various COVID-19 vaccines, including mRNA, DNA, protein- based, and inactivated virus vaccines. A comprehensive analysis of 27 studies and 24 case reports published until 2021 reveals that localized SEs, such as injection site pain, are prevalent, while systemic SEs like headache and fatigue are also common. The safety profiles of vaccines vary, with mRNA and DNA vaccines showing more persistent SEs compared to inactivated viral vaccines. Notably, SEs are reported to be more frequent among women and younger individuals. Despite the occurrence of adverse reactions, the majority of studies affirm the overall safety of COVID-19 vaccines, highlighting the need for ongoing research to establish the pathological links between vaccination and reported adverse effects.

KEYWORDS: Adverse effects, covid-19, lipid nanopartical, mRNA vaccine, SARS-CoV- 2, spike protein.

INTRODUCTION

A pandemic is considered a phenomenon having devastating effects on people and economics with many causalities. Pandemics are said to have both health and economic calamities 1. The first case of COVID-19 was registered in India on January 27, 2020. A nationwide lockdown was imposed in the country in the month of March 2020. The general public was being monitored for following the lockdown, social distancing, and wearing masks. As per the last year's records, it is established that by May 18, 2020, India registered 1 Lakh COVID-19 infected cases. However, within a span of less than 2 months the cases were increased by 8 times and India had 8 Lakh infected cases2. As of May 4, 2021, the number of confirmed cases of COVID 19 rose to 2,02, 82, 833 in India, and the death toll reaching 2,22,408 3. The above statistics make India the second largest affected country

in the world only after the United States of America. Currently, COVID-19 is spreading at a distressing rate in India. The spread of the deadly virus highlights the importance of.vaccination at a national level- The vaccination is supposed to protect the nation from continued damage. The Government has introduced the vaccination drive all over the country on January 16, 20214. The vaccination drive is being conducted in stages, focusing on health care workers and frontline staff in the first stage. They are at a supreme risk of getting exposed to the virus. The second stage focuses on elderly people above the age group of 45. They are at a high risk of getting affected owing to the virus. In the third stage, people in the age group of 18-45 will be targeted. Nationwide usage of two COVID-19 vaccines is approved, Covishield by Serum Institute of India and Covaxinmanufactured by Bharat Biotech. As per the official data, as of May 4, 2021, a total of 158932921 doses overall including both the first dose and second dose of the vaccine has been provided in India 8,9. 4,5,18 traditional vaccine development strategies:

1. **Vaccines are the biological molecules**- that induce an immune response against any infection or disease inside the body. Within the last few years, infectious diseases around the world have resulted in an increment of death rates and are known to be the major cause of mortality. Vaccination and immunization, the keystone of public health policy made a major contribution to global health19. Development of a vaccine involves the use of microorganisms responsible for the disease development either Live attenuated vaccines This is the traditional method of vaccine development containing whole bacteria or virus in its weakened form so as to build up a protective immune response .
2. **Live attenuated vaccines-** can be obtained by transferring the disease causing organism through a series of cell cultures or embryos of animals (chick embryos). The weakened organism replicates same as a natural infection thereby causing a humoral and cell mediated immune response. The live attenuated vaccines induce immune system.
3. **Inactivated vaccines**- These vaccines do not contain any live ingredient as they are produced from pathogens deactivated by formaldehyde or heat. These chemicals impair the replicative ability of pathogens but they can still be recognized by the host's immune system. To induce more immunogenicity booster doses are required as these candidates are less immunogenic. The vaccines developed agains t Hepatitis A, rabies, Salk polio and influenza are some important inactivated vaccines13.
4. **Protein subunit vaccines-** These vaccines use antigenic components (like spike protein) generated in vitro. They include only epitopes that trigger the immune system. This vaccine does not contain whole bacteria or virus so that immune response can target only a subset of pathogen protein with antigenic properties. Subunit vaccines do not create long lasting immune responses, hence require adjuvants and additional booster doses. Although peptide vaccines possess high efficacy and several advantages, yet
5. **Nucleic acid vaccines** are quick and easy to develop using genetic material from a pathogen.
6. **Viral vector vaccines** These vaccines are produced by isolating an antigen from pathogen and integrating it into a bacterial or viral vector system. The bacteria or virus behaves as a vector that replicates and expresses pathogenic gene inside the cell. Viral vector vaccines are grown on cell lines hence easily and cheaply developed. As viral vector vaccines produce endogenous antigen hence, activate both humoral and cellular immune responses in single dose. Viral vector vaccines depending on the replicating
7. **Toxoid vaccines**-Toxoid vaccines contain attenuated toxins inducing humoral immune response. The purification of bacterial toxins followed by their inactivation with formaldehyde leads to generation of a

toxoid, routinely used to make diphtheria and tetanus toxins. The inoculation with a toxoid, results in release of anti-toxoid antibody that readily binds and neutralizes its toxicity. Toxoid vaccines do not provide prolonged immunity, hence require regular booster doses for effective protection.

8. **Conjugate vaccines** Conjugate vaccines made by combining two distinct components, hence similar to recombinant vaccines. Bacterial coat fragments are coupled to a carrier protein that is utilized in vaccination. Conjugate vaccines elicit a stronger co-immune response whereas fragments of bacteria show less immunological response. This bacterial fragment does not cause disease, but provides protection against future infections when associated with carrier proteins. These vaccines are used in pneumococcal
9. **Outer membrane vesicles vaccine –**The outer membrane of Gram-negative bacteria, sometimes form extracellular vesicles (outer membrane vesicles, OMV) with a diameter of 20 to 300 nm. Since the driving factor for OMV development remained unclear for a long period, the establishment of OMVs still remains unclear.

OMV production assumed to be a random stress response from bacterial cells. In recent years, OMVs have attracted significant attraction in form of vaccine delivery system against bacterial infection

COVID-19 VACCINE DEVELOPMENT

Vaccine development, a long and complex process which takes years and even decades for successful vaccine formulation. However, the COVID-19 vaccine development program took a year and was a miracle across the globe. COVID-19 vaccine development was a big challenge for the researchers as it was targeted to develop a vaccine in a span of 12–24 months. The rapid development of COVID-19 vaccine was facilitated by well-timed release of viral genome sequence, advancement and innovation in Vaccine based on inactivated.

- SARS-CoV-2 virus SARS-CoV-2 is inactivated or killed by using different chemical techniques and the candidate vaccines under this group are injected intramuscularly. CoronaVaC by Sinovac Biotech It is a purified SARS-CoV-2, inactivated vaccine candidate which was previously known as PiCoVacc. It is designed by cultivating the SARSCoV- 2 CN2 Strain inside Vero cells and in activating it with βpropiolactone. According to the preclinical trials it stimulates SARS-CoV2 specific neutralizing antibodies (nAbs). Vaccine based on SARS-CoV-2 protein subunit
- Novavax (NVX-CoV2373) The Novavax COVID-19 vaccine, NVX-CoV2373, a type of protein subunit vaccine uses nanoparticle based vaccine, designed by Novavax and Coalition for Epidemic Preparedness Innovations (CEPI). These vaccines are under trial in India under the brand name Covovax. This US based Novavax Inc. has a manufacturing contract with Serum Institute of India. This vaccine is designed by creating an engineered baculovirus containing a gene for the modified SARS-CoV-2 spike protein. The Vaccine based on virus-like particle (VLP)
- Triple Antigen- Vaccine by Premas Biotech or Orovax vaccine Premas Biotech (India) in collaboration with Oramed Pharmaceuticals (Jerusalem) designed an oral vaccine to be swallowed as a pill instead of being injected. This is a VLP vaccine prototype which acts on 3 surface proteins of the SARS-CoV-2 virus, the spike, the membrane and the envelope protein. Premas known for developing recombinant proteins for vaccine development, such proteins are 'difficult to express' proteins (DTE-Ps). The Vaccine based on DNA
- INO-4800- This vaccine was developed by Inovio Pharmaceuticals in partnership with Beijing Advaccine Biopharmaceuticals Suzhou. This strategy utilizes codon optimized S protein sequence of SARS-CoV-2 to

which an IgE leader sequence is attached. The INO- 4800 vaccine contains the plasmid pGX9501 encoding the entire length of spike glycoprotein of SARS-CoV-2. Inovio's proprietary platform uses CELLECTRA, a brief electrical pulse to open small pores in the cell reversibly to allow the plasmids to Vaccine based on RNA

- mRANA− 1273 by Moderna 71 17 Spikevax, the brand name of mRNA-1273 vaccine, designed by Moderna, the United States National Institute of Allergy and Infectious Diseases (NIAID) and the Biomedical Advanced Research and Development Authority (BARDA). This vaccine comprises of synthetic mRNA enclosed in lipid nanoparticle (LNP) encoding the full length pre fusion stabilized spike protein (S) of SARS-CoV-2, therefore, stimulates a highly S-protein specific antiviral response. This vaccine is Vaccines based on viral vectors
- Ad5-nCoV-(CanSino Biologics Inc | Beijing Institute of Biotechnology) This is a non- replicating viral vector vaccine, administered with a single dose. This vaccine is based on CanSino BIO's adenovirus viral vector vaccine technology. The vaccine is designed by using the Admax system from the Microbix Biosystem. The CanSino Biologics Convidicea is a genetically engineered vaccine candidate with the replication defective adenovirus type 5 as the vector to express SARS-CoV-2 spike protein.

Table 1: Globally approved vaccines for COVID-19 until 13 August 2021.

Vaccine	Vaccine platform and formulation techniques	Target antigen	Immunogenicity	Efficacy	Dose and time interval	Reference
BNT162b2	RNA, nucleoside modification of SAS-CoV 2 mRNA	Spike protein	Both humoral and cell mediate responses	95%; 88% (against Delta variant); 93% (against Alpha variant)	2 doses, 3 weeks apart	10
mRNA-1273,	RNA encapsulation of SAS-CoV 2 mRNA in lipid nanoparticle (LNP)	Spike protein	Both humoral and cell mediate responses	94.1%; 100% (against Alpha variant); 96.4% (against Beta variant	2 doses, 4 weeks apart	10
Ad26.COV2.S	Non replicating viral vector, use recombinant and replication incompetent Adenovirus type 26 (Ad26) vector which encodes the SAS-CoV-2 spike (S) protein	Spike protein	Both humoral and cell mediate responses	67% in phase 3 study; 72% in US; 68.1% in Brazil study; 64% in South Africa Study	Single dose	27

Table 2: Reported Minor and Major Side Effects of COVID-19 Vaccines from Observational Studies and Adverse Event Registries

Sr no	Vaccine Name	Methodology	Participant/ Area	Date/ Duration	Minor Side Effects	Major Side Effects	Duration	Concluding	References
1	Covishield	Web-based self-report submission or vaccine event reporting system	5637 HCWs in India	16 January–6 February 2021	Mild fever, myalgia, cold, cough, headache, local pain, swelling, fatigue, diarrhea, rigors, joint pain, nausea		-		5
2	Sinovac	Questionn aire	355 nurses in Turkey	-	fatigue, headache, arthritis, sore throat, nausea, fever, vertigo, nasal flow, appetite changes, diarrhea, itchiness,		-		12

					abdominal pain, cough, changes in the mucosa, changes in taste sensation.				
3	mRNA vaccines	Online poll	2002	February 2021	Fever, dyspnea, flu-like illness, weariness, local reactions.	Few serious advers e effects such as anaphy laxis, in viral vector-based immuni zations.	-	mRNA vaccines linked with higher but milder incidence of any side effect.	10
4		VAERS	9442 reports of adverse events in the United States	March 2021	Dizziness, headaches, discomfort, muscular spasms, myalgia, paresthesia.	Stroke (17), GBS (32), facial palsy (190), transve rse myelitis (9 cases), acute dissemi nated enceph alomye litis (6 cases)	-	The rare occurrence of tinnitus, dysphonia, convulsion s, and herpes zoster recurrence was reported.	10

Table 3: Case studies with reported SEs of COVID-19 vaccinations.

Vaccine	Cases	Patient	Date/Duration	Complication/Side Effects	References
mRNA-based COVID-19 immunization	Case I (Pfizer-BioNTech COVID-19 vaccine)	47-year-old female	15 days after first dose	Lympho-proliferative disease: left infra-clavicular non-painful lump along with fatigue, myalgia, and mild pyrexia to 38 ◦C	[25]
	Case II (Pfizer-BioNTech COVID-19 vaccine)	46-year-old female	5 days after first dose	Left supraclavicular and axillary painful multiple enlarged lymph nodes, along with headaches, chills.	
	Case III (Pfizer-BioNTech COVID-19 vaccine)	42-year-old female	18 days after the first dose	Left axillary lymph nodes up to 2 cm in diameter	
mRNA-based COVID-19 immunization	Case I (Moderna COVID-19 vaccine)	64 -year-old female with a history of shellfish allergy	Within 10 min of the first dose	Hypersensitivity rection withgeneralized pruritus, urticaria, and self-reported tachycardia	[26]
	Case II (Moderna COVID-19 vaccine)	39-year-old female with history of allergic rhinitis	Within 15 min of the first dose	Reactionwith chest and neck urticarial and mild facial angioedema	
Inactivated COVID-19 immunization	One case (Sinopharm COVID-19)	18-year-old female with a history of antinuclear antibody positive oligoarticular juvenile idiopathic arthritis (JIA)	5 days after the second dose	Bilateral anterior uveitis with reduced visual acuity in both eyes	[34]

Viral vector-based COVID-19 immunization	One case (Janssen COVID-19 vaccine)	74-year-old male	3 days after the dose	Severe cutaneous adverse reaction with panhypopituitarism secondary to be craniopharyngioma resection, vision loss of the left eye, neurogenic bladder, and obstructive sleep apnea	[25]
Viral vector-based COVID-19 immunization	One case (Janssen COVID-19 vaccine)	41-year-old morbidly obese gentleman	Within four weeks of dose	n-Barré syndrome (GBS)	[28]
mRNA-based COVID-19 immunization	One case (Moderna COVID-19 vaccine)	72-year-old female	1 day after receiving the first dose	Idiopathic thrombocytopenic purpura with a rash, spontaneous oral bleeding, headache and easy bruising or abnormal bleeding.	[29]

COVID-19 Vaccinations Reported Minor Side Effects

As elaborated in Table 1,

1. The most-prevalent minor SE reported after COVID-19 vaccinations were localized reactions in the form of local injection site reactions.
2. Injection site/shoulder pain swelling, and soreness surrounding the area,whereas the mostprevalent generalized SEs were headache, fever, sweating, chills, tiredness, and fatigue.
3. There were minor SEs in the nose, throat, and oral cavity including throat infection or irritations, breath tightness, nasal stuffiness, flu-like symptoms, sensations of throat closure, oral mucosal lesions, paresthesia, and taste disturbance. The minor SEs of musculoskeletal symptoms included joint pain,muscular spasm, whole-body aches/myalgia, osteoarticular pain, back pain, and neck pain.
4. The SEs of skin included skin rashes or allergic responses of urticarial eruptions, morbilliform eruptions, and pruritus.[9]
5. The minor SEs of the gastrointestinal system included nausea, vomiting, and diarrhea, while other SEs reported include fast heartbeat, dizziness, flushing, palpitations, brain fogging, mental confusion, anorexia, decreased sleep quality, drowsiness, hand numbness, enlarged lymph nodes, etc.

COVID-19 Vaccinations' Reported Major Side Effects

The adverse or major-severity SEs in Tables 1 and 2-1) reported from COVID-19 vaccinations on skin included zoster or herpes simplex flares such as varicella-zoster virus reactivation, chilblains, cosmetic filler reactions, and pityriasis rosea.

1. The major SEs of the cardiovascular system (CVS) reported in studies include thromboembolic events such as thrombosis, cerebrovascular accidents, myocardial infarction, takotsubo cardiomyopathy, and pulmonary embolism.
2. The major SEs of the central nervous system (CNS) included CNS demyelination, multiple sclerosis, syncope, transverse myelitis, encephalopathy, stroke, and acute disseminated encephalomyelitis.
3. The major SEs of musculoskeletal system included Guillain-Barré syndrome, Bell's palsy and facial palsy.
4. Ocular adverse effects included episcleritis, anterior scleritis, acute macular neuroretinopathy, acute middle

maculopathy, subretinal fluid, and anterior uveitis associated with juvenile idiopathic arthritis (JIA).

5. Severe immune system disturbances and autoimmune side effects were also observed, such as antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis of acute kidney injury, severe immune thrombocytopenia, lympho-proliferative disease, hypersensitivity reaction, and severe cutaneous adverse reaction with panhypopituitarism secondary to craniopharyngioma resection. Furthermore, among adverse reactions, COVID arm with pruritic, erythematous plaques were reported.
6. However, the link between the mildness and severity of SEs, along with the mechanism involved and other risk factor associations, is still under debate and requires proper investigative studies.

Advantages of COVID-19 Vaccination-

- Boost the immunity by creating an antibody
- Prevent and reduce the risk of severe illness
- Reduce the risk of death from COVID-19
- Reduce the risk of spreading

CONCLUSION

The COVID-19 pandemic has had a devastating impact on India, with a significant increase in cases and casualties over the past year. The rapid spread of the virus has underscored the critical importance of a national vaccination drive to mitigate the ongoing damage. The government's initiative to roll out the vaccination drive in stages, prioritizing healthcare workers, frontline staff, and high-risk age groups, is a crucial step towards curbing the spread of the virus. Additionally, the approval and distribution of various types of COVID-19 vaccines, such as inactivated, protein subunit, nucleic acid, and viral vector vaccines, have provided essential tools in the fight against the pandemic. However, the reported minor and major side effects of COVID-19 vaccinations highlight the need for continued monitoring and research to ensure the safety and efficacy of the vaccination programs.

CONFLICT OF INTEREST

The authors have no conflicts of interest regarding this investigation.

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