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A Survey on the Side Effects of COVID-19 Vaccination in the Northern Region of India

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Abstract

In order to assess the adverse effects of COVID-19 vaccination, a cross-sectional study was carried out in northern India. Information was gathered from those who had at least one COVID-19 vaccination dosage. Data on vaccination type, post-vaccination side effects, and demographic variables were analyzed. Fever, headaches, exhaustion, and local injection-site reactions were among the mild to severe adverse effects that were most frequently reported. Adverse effects that were severe were uncommon. While offering information on the incidence and kind of side effects in the group under review, this study emphasizes the general safety of COVID-19 vaccinations.

1. Introduction

Coronaviruses are members of the Nidovirales order's Coronaviridae family. The term "coronavirus" refers to the spikes on the virus's outer surface that resemble crowns. The single-stranded RNA that makes up the nucleic material of coronaviruses is tiny (65–125 nm in diameter) and ranges in size from 26 to 32 kbs. The coronavirus family has four subgroups: delta (δ), gamma (γ), beta (β), and alpha (α) coronaviruses Acute lung injury (ALI) and acute respiratory distress syndrome (ARDS) are caused by the Middle East respiratory syndrome coronavirus (MERS-CoV), H5N1 influenza A, H1N1 2009, and severe acute respiratory syndrome coronavirus (SARS-CoV). These illnesses ultimately lead to pulmonary failure and death[1].

2. COVAXIN

The inactivated vaccine Covaxin (BBV152) was created by the Indian pharmaceutical company Bharat Biotech in association with the Indian Council of Research (ICMR) and the National Institute of Virology (NIV).[2] The vaccine was created utilizing technology developed from whole virion inactivated Vero cells and a toll-like receptor 7/8 agonist molecule adsorbed to alum (Algel-IMDG).[3] ,[4] The NIV-2020-770 strain, which has a GISAID sequence (EPI_ISL_420545), was obtained from "Vero CCL-81" cells.[5] ,[6] It makes use of a whole infectious SARS-CoV-2 viral particle that contains dead virus that cannot infect but has RNA encased in a protein shell.[7] In July 2020, DCGI assigned the vaccine for two doses spread over 28 days in Phase I and Phase II human clinical studies.[3]

Covaxin is composed of up of 6 µg of entire virion inactivated SARS-CoV-2 antigen, 250 µg of aluminum hydroxide gel, 15 µg of TLR 7/8 agonist (imidazoquinoline), 2.5 mg of 2-phenoxyethanol, and up to 0.5 ml of phosphate buffer saline. The coronavirus sticks were made and immersed in beta-propiolactone. This substance prevented coronaviruses from reproducing, although their spike and other proteins were unaffected. After receiving a vaccination, antigen-presenting cells absorb part of the inactivated viruses. The APCs digest the coronavirus and display it on their surface so that T-helper cells can recognize it. When proteins on the surface of B cells attach themselves to the

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coronavirus, the B cell locks on, pulls a portion of the virus inside, and displays coronavirus fragments on its surface. The B cells multiply and create antibodies that can target the spike proteins once they become active.[8]

BBV152 produced an impressive neutralizing antibody response in a Phase I clinical trial against the homologous hCoV-19/India/2020770 and two heterologous strains from the unidentified cluster, hCoV- 19/India/2020Q111 and hCoV-19/India/2020Q100.[6] In a Phase II clinical trial, the vaccine demonstrated noteworthy outcomes in the plaque reduction neutralization test (PRNT50)-based assay using 6 and 3 antigen in imidazoquinoline (TLR7/TLR8 agonist adsorbed on aluminum hydroxide gel).[4] The Indian Council of Medical Research (ICMR) released a press release on March 3, 2021, stating that the Covaxin Phase III data indicated an interim vaccination effectiveness of 81%.

In addition to inducing a T helper cell 1-based antibody response, the formulation containing the toll-like receptor 7/8 agonist significantly increased numbers of CD4 cells and interferon gamma specific to SARS-CoV-2. Covaxin has demonstrated its ability to neutralize the following variants: B.1.1.7 (Alpha), B.1.617 (Kappa), B.1.351, B.1.617.2 (Beta & Delta), P.1-B.1.1.28 (Gamma) & P.2-B.1.1.28 (Zeta). Covaxin is 93% effective against severe illness and provides 65.2% protection against the SARS-CoV-2, B.1.617.2 Delta variant, according to effectiveness studies.[3]

3. COVISHIELD

The non-replicating viral vaccine Covishield (AZD1222) was created at the Jenner Institute at the University of Oxford in the United Kingdom and is licensed by the British pharmaceutical firm AstraZeneca. On January 3, 2021, Covishield received its initial approval for restricted usage. The Oxford University-developed AZD1222 (ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)) is made up of the SARS-CoV-2 surface glycoprotein gene and the replication-deficient chimpanzee adenoviral vector ChAdOx1.[9]

L-histidine, L-histidine hydrochloride monohydrate, magnesium chloride hexahydrate, Polysorbate 80, ethanol, sucrose, sodium chloride, EDTA, and water for injection were used to create the Covisheld vaccination. A modified form of chimpanzee adenovirus (ChAdOx1), which may enter cells but cannot reproduce there, was employed by the Oxford-AstraZeneca research. For at least six months, the vaccination can be stored in a refrigerator between 38 and 46 °F. Following the injection of the vaccine, the adenovirus comes into contact with the cells and attaches itself to surface proteins. The virus enters the cell by swallowing it in a bubble. Once inside, it exits the bubble and travels to the nucleus, which houses the cell's DNA. While the coronavirus spike protein replicates itself, the adenovirus cannot reproduce itself despite pushing its DNA into the nucleus. The immune system uses these projecting spikes and spike protein fragments as recognition particles. Antigen- presenting cells can absorb spike proteins and fragments from the damaged cells that remain after the vaccinated cell dies. When B cells come into contact with coronavirus spikes, helper T cells may activate them, producing antibodies and preventing infection by preventing the spikes from adhering to other cells.[8]

According to the phase 3 trial, the group that received a low first dose vaccination followed by a standard second dose showed 90.0% efficacy, while the group that received a standard dose followed by a booster dose showed 62.1% efficacy. As a result, the overall efficacy at least two weeks after the second dose of vaccine was calculated to be 70.4%.

4. SPUTNIK V

The Gamaleya National Research Centre for Epidemiology and Microbiology of the Russian Federation's Ministry of Health in Moscow, Russia, created the non-replicating vector vaccine known as Sputnik V (Gam- COVID-Vac). Researchers added the coronavirus spike protein gene to two different adenoviruses, Ad26 and Ad5, and altered them so they could enter cells but not reproduce. Using two different serotypes is a special method that increases the immune response and offers effective long-term immunity. To increase immunological response, the first dose (based on Ad26) is injected on the first day, and the second dose (based on Ad5) is given on the second.[10],[11]

After the second dosage, the Moscow vaccine experiment showed a 91.6% effectiveness rate for all age categories with no noteworthy side effects.[12] The Russian Ministry of Health stated in July 2021 that Sputnik V was 83.1% effective against the Delta variant and demonstrated a six-fold decrease in the probability of infection. Phase III clinical trials of Sputnik V showed that 98% of recipients developed a humoral immune response and 100% acquired a cellular

immunological response following vaccination. On June 4, 2021, DCGI granted Serum Institute of India permission to produce Sputnik V COVID-19 at its Hadapsar facility.

With a population of 1.3 billion, vaccination is a difficult challenge in India. Prime Minister Shri Narendra Modi said on June 21 that everyone in India above the age of 18 would receive a free vaccination. Although the vaccination campaign is gaining traction in India, the success of any immunization program is largely dependent on the public's acceptance of the vaccines and their level of trust. Myths and false information are spreading on various platforms, causing some people all over the world to be reluctant to get vaccines. The Indian government has previously launched a number of awareness programs to dispel reluctance and build public trust in vaccinations. In order to expedite the immunization process, the Indian government created the Co- Win digital platform, which allows users to schedule vaccination appointments, obtain reliable information, and monitor vaccine progress.[10]

5. Side Effect

5.1. Covishield

In 20 UK facilities, a single-blind, randomized, controlled clinical trial including recipients of the Covishield vaccine revealed reports of both local and systemic responses, including headaches, muscular aches, injection site pain, and a feverish feeling. [13] Compared to younger persons, elderly adults (those over 56) experienced fewer reactions. Health care workers, those over 60, and people with co-morbid disorders between the ages of 45 and 59 were the priority groups vaccinated in India. [14]

Post-vaccination symptoms were experienced by 95.1% of the responders. Injection site discomfort (79.8%), myalgia (67.2%), fatigue (64.6%), fever (48.9%), headache (15%), nausea (14.7%), giddiness (13.1%), diarrhea (6.2%), and redness at the injection site (5.3%) were the most frequent complaints. Anaphylaxis, peri-orbital edema, dyspnea, vomiting, and the passing of red urine were among the uncommon symptoms that were observed.[15]

5.2. Covaxin

When compared to other COVID-19 vaccinations, the adverse effects of Covishield and Covaxin are "less than negligible," according to Aayog, a member of the National Institute for Transforming India (NITI). Following both vaccinations, the most frequent side effects were headache, joint discomfort, muscular soreness, redness at the injection site, and slight fever.[16] Despite the public awareness campaign about the value of vaccination, a number of variables limit the population's adherence to this intervention, including long-term adverse outcomes from these vaccines that increase worry and vaccine reluctance.[17]

5.3. Sputnik V

The Sputnik V has nearly identical side effects. Injection site soreness, fever, headaches, exhaustion, and joint and muscle pain are the most frequent adverse effects of Sputnik V.[18]

6. Aim

To assess and analyse the side effects experienced after COVID-19 vaccination among individuals in the Northern region of India.

6.1. Objectives

1. To document the types and frequency of side effects following COVID-19 vaccination.

2. To compare side effects based on age, gender, and type of vaccine received.

3. To identify any rare or severe adverse events post-vaccination.

7. Methodology

The study comprised 119 patients in total. Data on vaccine kind, gender distribution, and post- vaccination side effects were gathered. There were four severity classifications for adverse effects: No, Mild, Moderate, and Severe.

Gender Distribution

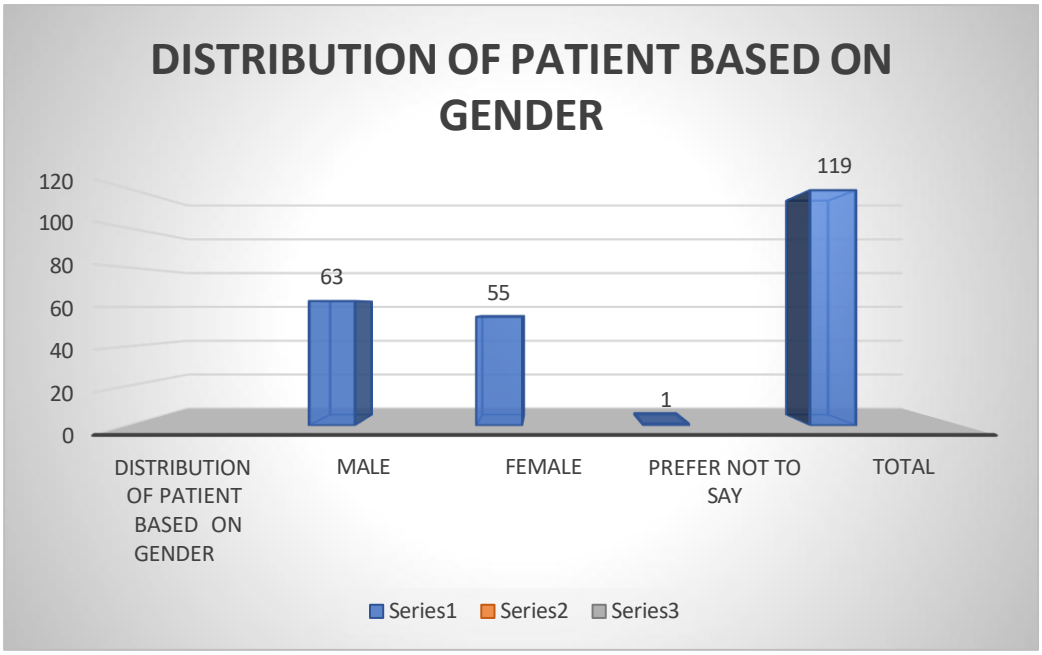
Gender	Count	Percentage	Total
Male	63	52.9%	119
Female	55	46.2%	119
Prefer not to say	1	0.9%	119

Vaccine Distribution

Vaccine	Count	Percentage
Covaxin	85	71.4%
Covishield	8	6.7%
Sputnik V	26	21.9%

Adverse Effects Summary

Adverse Effect	No (%)	Mild (%)	Moderate (%)	Severe (%)
Fever	42.01	30.25	16.80	10.92
Generalized Weakness	39.49	36.13	17.64	6.72
Rashes	100	0	0	0
Chills	73.10	15.12	6.72	5.04
Headache	63.02	20.06	4.20	12.60
Body Pain	41.18	25.21	19.33	14.29
Nausea	95.80	4.20	0	0
Diarrhea	96.60	1.68	0.84	0.84
Runny/Blocked Nose	92.43	6.72	0.84	0



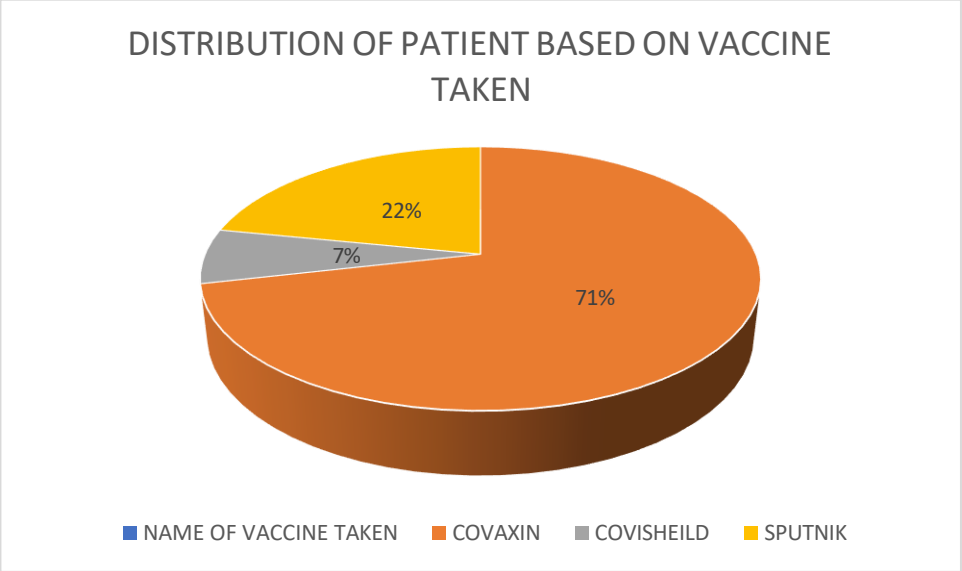
Interpretation

Distribution of patient based on gender

MALE	63
FEMALE	55
PREFER NOT TO SAY	1
TOTAL VACCINATED	119

% of gender distribution = male (52.9%) female (46.2%) prefer not to say (0.9%)

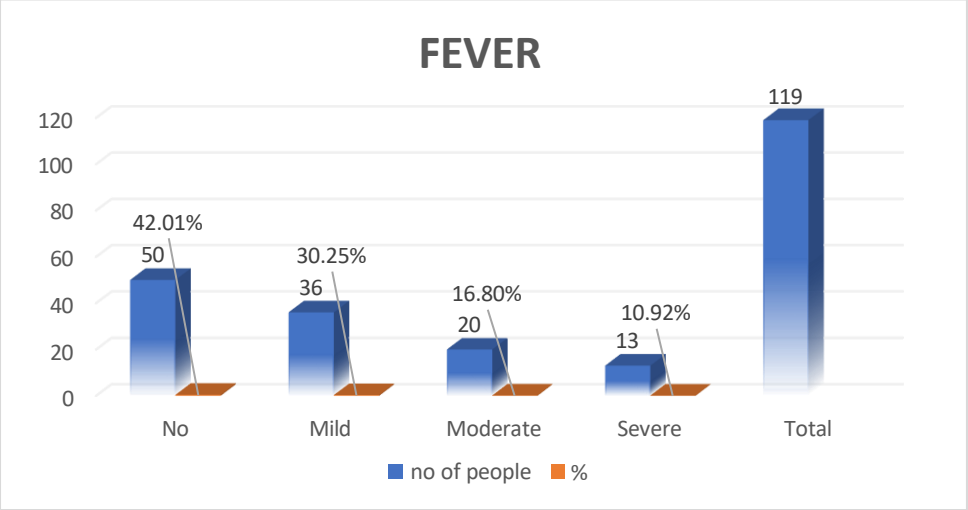
NAME OF VACCINE TAKEN	
COVAXIN	85
(COVISHEILD	8
SPUTNIK V	26



% of Distribution of Vaccine taken= Covaxin (71.4%), Covishield (6.7 %) , Sputnik (21.9%)

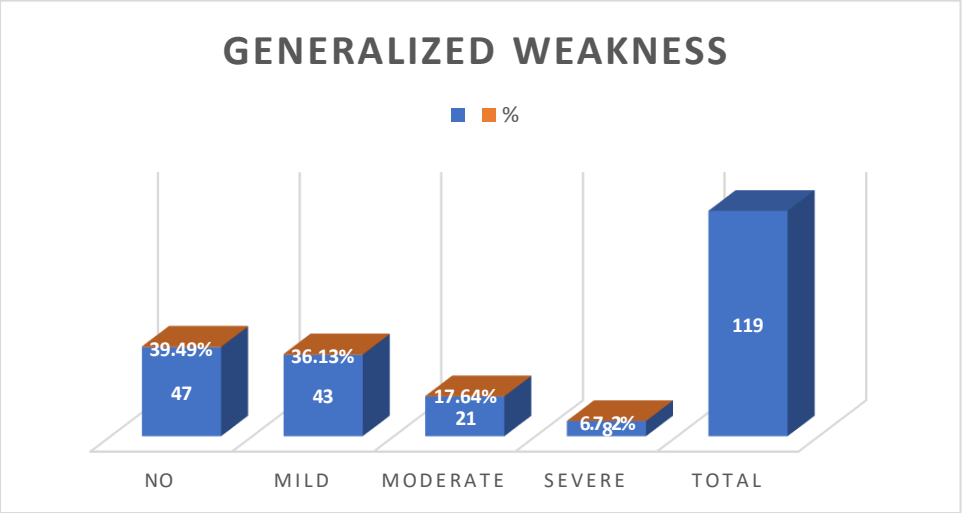
Distribution based on severity of symptoms observed

Fever	no of people	%
No fever	50	42.01%
Mild	36	30.25%
Moderate	20	16.80%
Severe	13	10.92%
Total	119	



Interpretation: Most patients either had no fever (42%) or only mild fever (30%) after vaccination moderate (17%) and severe fever (11%) were less common.

Generalized Weakness		%
No	47	39.49%
Mild	43	36.13%
Moderate	21	17.64%
Severe	8	6.72%
Total	119	



Interpretation: A large share reported no weakness (39%)

Mild weakness (36%) was nearly as common

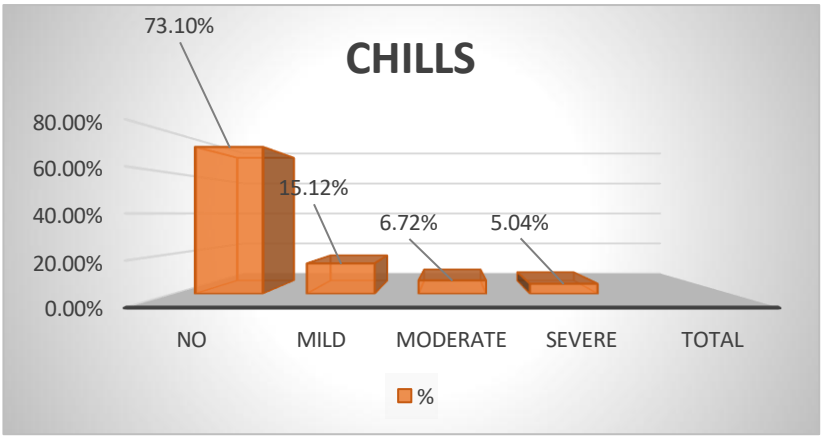
Moderate (18%) and severe (7%) weakness were less frequent

Rashes all over the body: **No**

Interpretation:

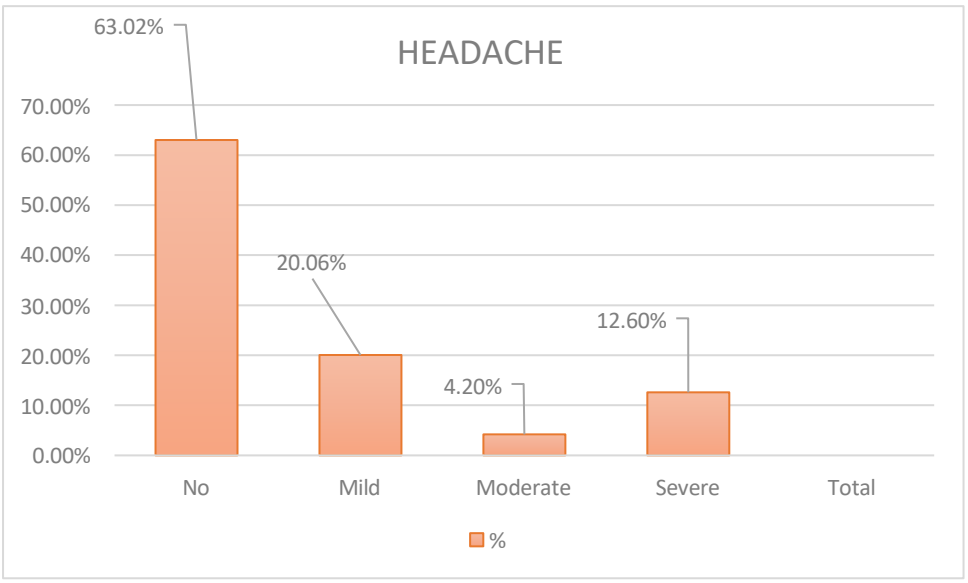
None of these 119 vaccinated patients have developed with the symptoms of rashes.

Chills	No of People	%
No	87	73.10%
Mild	18	15.12%
Moderate	8	6.72%
Severe	6	5.04%
Total	119	



Interpretation: Most patients (73%) did not experience chills. Mild chills occurred in ~15%, while moderate (7%) and severe (5%) were less frequent.

Headache	No of People	%
No	75	63.02%
Mild	24	20.06%
Moderate	5	4.20%
Severe	15	12.60%
Total	119	



Interpretation:

Majority (63%) reported no headache.

Around 1 in 5 (20%) experienced mild headache.

Severe headache (13%) was more common than moderate headache (4%)

Body Pain	
No	49
Mild	30
Moderate	23
Severe	17
Total	119

Interpretation:

About 41% had no body pain.

59% experienced body pain of varying severity (mild to severe).

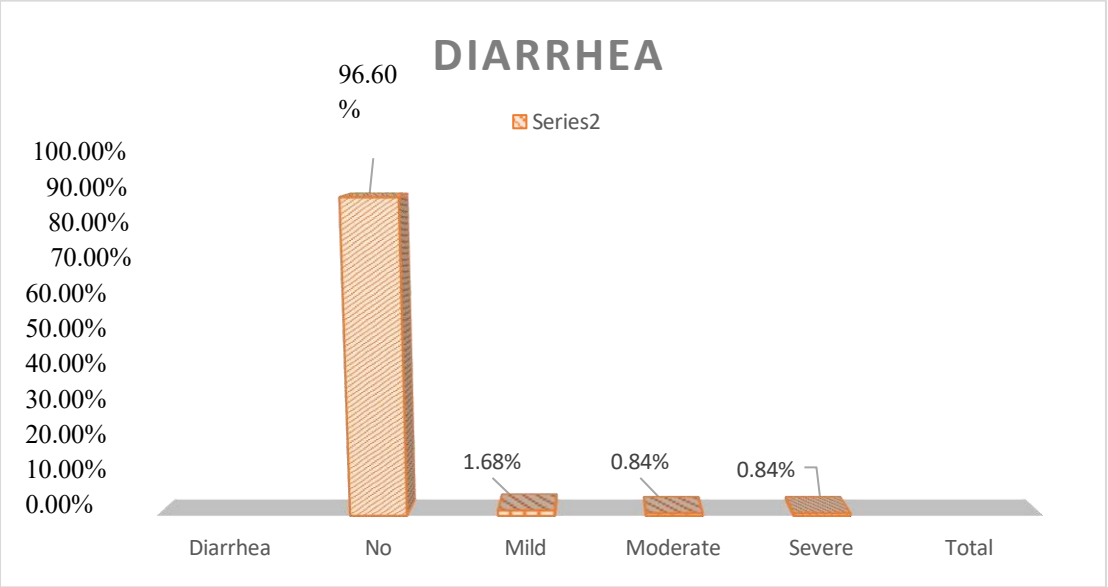
Mild pain (25%) was the most common, but severe pain (14%) was also relatively high compared to other adverse effects.

Nausea	
No	114
Mild	5
Mod	0
Severe	0
Total	119

Interpretation:

Almost everyone (96%) reported no nausea. Only a few (4%) had mild nausea, and no cases of moderate or severe nausea were observed.

Diarrhoea		
No	115	96.60%
Mild	2	1.68%
Moderate	1	0.84%
Severe	1	0.84%
Total	119	



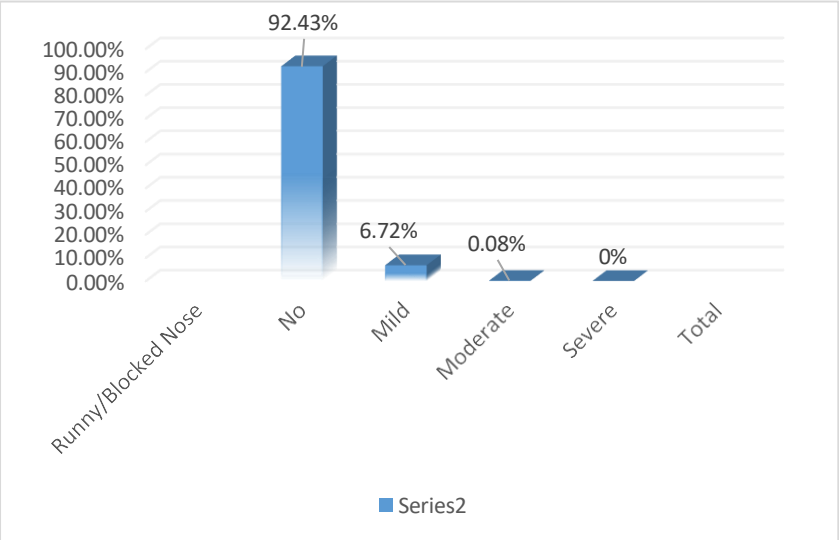
Interpretation:

Almost all patients (97%) reported no diarrhoea.

Very few had mild (1.7%), moderate (0.8%), or severe (0.8%) diarrhoea

Runny/Blocked Nose

No	110	92.43%
Mild	8	6.72%
Moderate	1	0.08%
Severe	0	0%
Total	119	



Interpretation:

This symptom did not appear in the majority of patients (92%). While moderate and severe instances were extremely uncommon, a small percentage (7%) had mild cases.

8. Summary & Discussion of Adverse Effects After COVID Vaccination (n = 119)

In this study, 119 recipients of the COVID-19 immunization were evaluated for side effects.

Fever (58%), headache (37%), bodily pain (59%), and widespread weakness (61%) were the most frequently reported adverse effects.

Most of these cases were mild to moderately severe.

Although severe side effects were comparatively rare, they were most frequently associated with fever (11%), headache (13%), and bodily discomfort (14%).

Less common side effects included chills (27%), nausea (4%), diarrhea (3%), and runny/blocked nose (7%). Crucially, there were no reports of rashes.

Interpretation: The results indicate that only a tiny percentage of COVID vaccine recipients experienced severe symptoms, with the majority of side effects being mild and self-limiting. This suggests that the vaccinations used in the study population (Covaxin, Covishield, and Sputnik V) had a favorable safety profile.

9. Conclusion

According to the current study, the COVID-19 immunization was generally well tolerated, with the majority of side effects being mild to moderate. Fever, headaches, and body aches were the most common severe adverse effects. The vaccinations' overall favorable safety profile supported their continuing widespread usage.

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