WWW.IJRPR.COM

International Journal of Research Publication and Reviews

Journal homepage: www.ijrpr.com ISSN 2582-7421

Adverse Events Following Covid Vaccination among Adult Population

Prof (Dr) Bishnupriya Mohanty[1], Shloka Ramesh Tirodkar[2*]

[1]MD (Samhita), PhD (Basic Principle), Professor and Head, Department of Sanskrit Samhita and Siddhanta, Gomantak Ayurveda Mahavidyalaya and Research Centre ; Shiroda, Goa. 403103
drbishnupriyadas@gmail.com
[2]UG Scholar Department of Sanskrit Samhita and Siddhanta, Gomantak Ayurveda Mahavidyalaya and Research Centre ; Shiroda, Goa. 403103 shlokatirodkar011@gmail.com

ABSTRACT

The goal of the study was to see how often adverse reactions to the covid vaccination are in the general population. Gomantak Ayurveda Mahavidhyalaya Research Centre, Shiroda Goa, undertook this cross-sectional study. Adult populations who had received the first and second doses of the vaccine and had been 28 days after the completion of the second dose met the inclusion criteria. Based on a pre-designed questionnaire, the inclusion criteria were asked to each person individually. The difference between the frequencies of adverse events after the first and second doses of vaccine was statistically significant. The most prevalent side effect was pain at the injection site. All of the symptoms were minor and only lasted two days. Age and comorbidities were found to be significant predictors of adverse outcomes. There were no vaccine-related life-threatening adverse events or symptoms of vaccine-related blood clotting in either dosage. Because no substantial life-threatening side events were reported, this study may help reduce public apprehension about immunization, hence reducing the spread of this extremely contagious virus.

Keywords : COVID 19. Vaccination . Adverse Events . Oxford AstraZeneca

Introduction

SARS-Cov 2, the deadly virus that causes Coronavirus Disease 19 (COVID-19), has spread widely around the world. Millions of individuals have been infected by the pandemic, which has resulted in more than 3 million deaths so far this year. Two vaccines developed in India have been given Emergency Use Authorization. These were ChAdOx1 CoV-19 VACCINE - Covishield (created by Oxford-AstraZeneca and manufactured by Serum Institute of India- SII) and Covaxin (developed by Oxford-AstraZeneca and manufactured by Serum Institute of India- SII) (manufactured by Bharat Biotech Limited).

On January 16, 2021, India began a phased COVID-19 vaccination campaign using Covishield and Covaxin vaccinations. In phase I, the goal was to vaccinate health care workers (HCW) before moving on to frontline workers. People above the age of 60, as well as those between the ages of 45 and 59 who have additional ailments, were addressed in phase II.

Corona Virus inactivated is included in Covaxin. Covishield is made utilizing a viral vector platform in which a chimp adenovirus called ChAdOx1 is engineered to transport the COVID-19 spike protein into human cells. This inactivated virus is unable to infect the recipient, but it does prepare the immune system to respond to viruses of this type. The Serum Institute of India published fact sheets about Covid-19 vaccine "adverse effects."

The study's goal is to see if there are any adverse effects post vaccination (AEFI) among Health Care Workers (HCW) who have received two doses of Covishield.We also evaluated the association of AEFI according to various demographic variables (sex, profession and age groups).

Adult vaccination drive has never been undertaken on sucha scale. Therefore, the acceptability of the vaccine as well as the safety concern regarding the vaccine has to be evaluated. Even though there has been some acceptability, vaccine hesitancy, defined as the vaccine acceptance is prolonged or refusal to accept the service of vaccination, is a feature among the people.

There is also a need to rule out certain misconceptions regarding the side effects of the vaccine that need to be addressed to prevent vaccine hesitancy. Therefore, this study was conducted among vaccinated persons regarding the post-vaccination adverse events and severe adverse events for the safety of the vaccinated persons as well as for future policy planning and implementation.

Methods

Study Design, Setting, and Participants

Thiscross-sectional study was conducted at GOMANTAK AYURVEDA MAHAVIDHYALA RESEARCH CENTRE, SHIRODA GOA.From 1st to 31st Oct 2020. A total of 110 persons aged 18 years and older received the 2nd dose ofvaccine, and in 28 days passed from the last dose, they were approached through online mode (whatsapp).

Sampling Technique

A list of persons who completed the 1st as well as 2nd dose of vaccine and completed 28 days post-vaccination was approached over the phone calls to collect the data from them. At least two attempts of calling were made for two consecutive days after 1st as well as 2nd dose. 10 % people did not respond to the call. Finally 100 persons were enrolled for the survey.

Inclusion criteria

Age >18 years, received two doses of vaccine.

Exclusion criteria

Age <18 years, not completed both doses of vaccine, recently hospitalized in last 14 days, past COVID-19 infections, pregnant and lactating women.

Data Collection

Data collection was done after the 1st dose and 2nd dose of vaccination. The participants were asked over the telephone using a predesigned structured questionnaire. Data regarding sociodemographic characteristics, comorbidities, adverse events of vaccination (both the doses), and diagnosis of COVID-19 were collected.

The types of adverse events collected were local, general, medically attended, and serious adverse events. The local adverse events included pain, swelling, itching, and rash at the injection site. General adverse events included fever, chills and rigors, generalized body ache, fatigue, malaise, , drowsiness, headache, nausea, vomiting, diarrhea, dizziness, joint pain, runny nose, and redness of the eyes. Medically attended adverse event was defined if a medical practitioner was consulted for managing the adverse events.

If an incident ended in death, was life-threatening, needed in-patient hospitalization or the prolonging of an existing hospitalization, resulted in permanent or major disability/incapacity, or was a congenital anomaly/birth defect, it was classified as serious. The severity of the adverse events was graded on a range of 0 to 10 on a numerical rating scale (NRS).Zero was depicted as having no symptom, 1–3 as mild symptoms, 4–6 as having moderated symptoms, and 7–10 as severe symptoms. The diagnosis of COVID-19 was based on RT PCR for SARS COV-2 test .

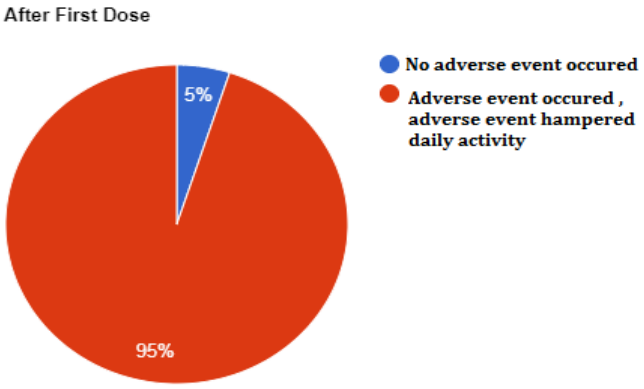
Reporting of adverse effects

Active and passive surveillance of the adverse events were done. The recipients were observed for 04 weeks after each dose of vaccine for the development of any adverseevents.

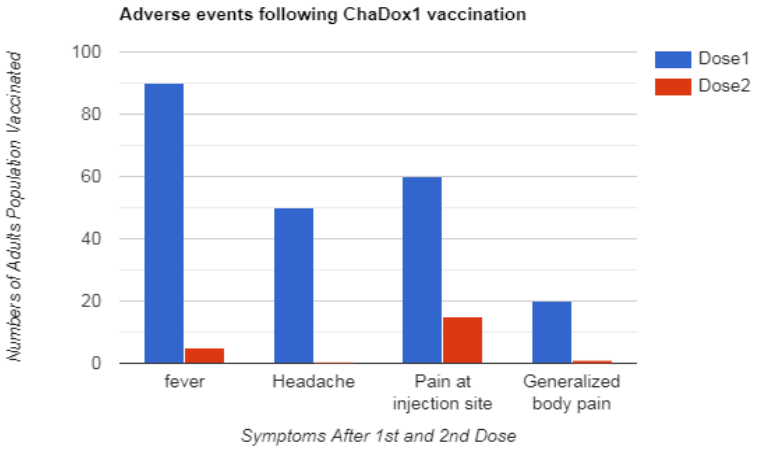
Adverse Events after Vaccination (n=100)

	After 1st dose	After 2nd dose
Adverse events occurred	95%	20%
No adverse events seen	5%	40%
Pain at injection site	60%	15%
Fever	90%	5%
Fatigue	3%	2%
Generalized body ache	20%	1%
Headache	50%	-
Swelling at injection site	10%	1%
Itching and rash at injection site	25%	2%
Dizziness	6%	-
Nausea	10%	5%
Vomiting	10%	3%
Diarrhea	1%	5%
drowsiness	5%	-
Running nose	6%	-
Redness of eyes	2%	-
Joint pain	55%	6%
Medication needed to manage adverse effects	90% (Dolo 650, Crocin tablet)	10%
Consulted medical practitioner for managing adverse events	10%	2%
Adverse event hampered daily activity	95%	7%

Pie- Chart



Bar Graph



Results

Among the 100 participants, The ratesof adverse events were 95% and 20% after the 1st and 2nddoses of vaccine, respectively. The adverse events were significantlyhigher following the 1st dose compared to the 2nddose. The most frequent adverse event was fever among 90% after the first dose of vaccine following the 60% pain at injection site. 5% people had got fever after 2nd dose of vaccination and 15% people had pain at injection site after 2nd dose of vaccination. Fatigue, generalized body ache, headache and joint pain were recorded. 3%, 20%, 50%, 55% respectively following the first dose of vaccination whereas after second dose these were reported 2%, 1%, 0, and 6% which showed the adverse events occurred in significantly less during the second vaccination. However none of the participants had severe life-threatening adverse events. Noneof them had symptoms related to thrombosis as well.

Almost 90% of participants needed medication namely dolo 650, crocin to get rid of symptoms after 1st dose of vaccination. 10% needed medication namely paracetamol to get rid of the symptoms after 2nd dose of vaccination. 10% participants had to consult the medical practitioners after the first dose of vaccination.

Significant number of participants had their daily activities hampered following the first dose in contrast to the 2nd dose (after first dose =95%) (after 2nd dose = 7%). 3% participants had covid 19 after 1st dose and 1% participants had covid 19 after 2nd dose of vaccination. None of the patients who suffered from covid 19 became critically ill.

Discussion

This study demonstrates that the rates of Adverse event of the COVISHIELD vaccine were 95% after the 1st dose and 20% after the 2nd dose of the vaccine. However, these were minor adverse events like pain at the injection site ,fever, feeling unwell,and generalized body ache . There were no significant life - threatening adverse events after vaccine administration**.**

Given the outcome of the phase 3 trial in the UnitedKingdom (UK), Brazil, and South Africa, the ChadOx1 vaccine had demonstrated 63% efficacy against symptomaticCOVID-19 cases, with acceptable tolerability and no serious adverse event related to vaccination . Adverse events recorded in our study were compared to the anticipated adverse events by the World Health Organization (WHO) SAGE working group based on phase 3 clinical trials in the UK, Brazil, and South Africa and phase 1/2 trial in the UK, and there were significant differences . In the WHO Working Group,the headache had been observed among 52.6% of participantswhile the phase 1/2 trial found 68% of participants

Compared to that, our study found only 50% of the studypopulation complained of headache following the vaccination.Another adverse event chill was present among 31.9% by theWHO Working Group paper and 56.4% among the phase 1/2trial, . Pain at the injection site was present among 60 % and 15% of participants from our study, while compared thatwith the WHO Working SAGE Working Group paper and phase 1/2 trial in the UK reported 54.2% and 67%, respectively. Nausea as an adverse event following the vaccination hadbeen reported only among 10% and 5% of our participants; comparedthat with the WHO SAGE Working Group and phase 1/2 trialin the UK, it was reported 21.9% and 25%, respectively Phase 1/2 trial in the UK found generalized body painamong 60% of participants, and the WHO SAGE WorkingGroup paper anticipated this adverse event to be reportedamong 44% of the population. In our study, we only recorded 20% and 1% population reported this adverse event .

When comparing the adverse event from the 1st dose and2nd dose of vaccination, according to the WHO SAGEWorking Group, adverse events that occurred more than10% are being denoted as very common, and from 1 to 10%are being termed as common. By that classification, pain at theinjection site (60%), fever (90%), Headache (50%) and generalized body ache (20%) were the very common adverseevents following the 1st dose of vaccination, while joint pain (6%), headache (0), chill (5%), pain at the injectionsite (15%), and nausea (5%) were common adverse events in our study

Limitation of the Study

No immediate allergic reaction following vaccination was recorded,and there had not been any incidents of anaphylactic reaction or shock following the vaccination. This also denotesthe allergic reaction to the components of the vaccine is minimum,but the scale of the population may give us limitedknowledge. It was exposed to transverse myelitis and pyrexia during the early stages of vaccine development, however neither of these conditions were observed in our research sample. Immunothrombosis after vaccination has been documented as a very unusual adverse effect after immunization in people with low platelet counts; however, none of the people in the research showed any signs of this illness. Due to the rarity of these adverse occurrences, our study population data may be limited in this aspect, necessitating additional research with a larger population.

Conclusion

These findings demonstrate that the vaccine is a well-tolerated and safe vaccination that may be administered to the adult population. Because no substantial life-threatening side events were recorded, this study may help lessen vaccine apprehension among the general public, hence reducing the spread of this highly contagious disease.

Acknowledgements

The authors would like to acknowledge allrespected respondents for their valuable time and participation in thisresearch work.

References

1. Worldometer. https://www.worldometers.info/coronavirus/.

2.COVID-19 vaccine tracker. https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape

3.COVAX explained. https://www.gavi.org/vaccineswork/covaxexplained

4. Riad A, Pokorná A, Attia S, Klugarová J, Koščík M, KlugarM.Prevalence of COVID-19 vaccine side effects among healthcareworkers in the Czech Republic. JClin Med. 2021;10(7):1428.

5. World Health Organization (2020) COVID-19 vaccines: safety surveillance manual.

6. Hjermstad MJ, Fayers PM, Haugen DF, Caraceni A, Hanks GW,Loge JH, et al. Studies comparing Numerical Rating Scales, VerbalRating Scales, and Visual Analogue Scales for assessment of painintensity in adults: a systematic literature review. J Pain SymptomManag. 2011;41(6):1073–93.

7. Ramasamy MN, MinassianAM, Ewer KJ, Flaxman AL, FolegattiPM, Owens DR, et al. Safety and immunogenicity of ChAdOx1nCoV-19 vaccine administered in a prime-boost regimen inyoungand old adults (COV002): a single-blind, randomised, controlled,phase 2/3 trial. Lancet. 2020;396(10267):1979–93.

8. World Health Organization (2021) COVID-19 vaccine explainerCOVID-19 vaccine ChAdOx1-S [recombinant], Developed byOxford University and AstraZeneca.

9. World Health Organization Background paper on COVID-19 vaccinesprepared by the Strategic Advisory Group of Experts (SAGE)on Immunization Working Group on COVID-19 vaccines

10.Poortahmasebi V, Zandi M, Soltani S, Jazayeri SM. Clinical performance of RT-PCR and chest CT scan for COVID-19 diagnosis; a systematic review. Adv J Emerg Med. 2020;4(2s):e57.

11.Yuki K, Fujiogi M, Koutsogiannaki S (2020) COVID-19 pathophysiology: a review. Clin Immunol:108427

12. Chen N, Zhou M, Dong X, Qu J, Gong F, Han Y, et al.Epidemiological and clinical characteristics of 99 cases of 2019novel coronavirus pneumonia in Wuhan, China: a descriptivestudy. Lancet. 2020;395(10223):507–13.

13. Khalil M, Gain G, Mahbub-Uz-Zaman K, Karim M, Sarker K,Akter D, et al. Gastrointestinal manifestations among COVID-19patients in Bangladesh: a cross sectional