Original Article

Adverse Events among Beneficiaries who Received a Dose of Sputnik V Vaccine at a Tertiary Care Hospital in Coastal Karnataka, India

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Abstract

Introduction: Vaccination has played a vital role in containing the COVID-19 pandemic. Sputnik V was the third vaccine approved for emergency use in India. The objectives of the present study were to document the adverse events following Sputnik V vaccination and the factors associated with adverse events. **Methodology:** This cross-sectional study was conducted during September and October 2021 in a teaching hospital of Karnataka. Ethics approval and CTRI registration were obtained before collecting the data. All persons receiving at least one dose of vaccine were invited to participate and baseline information was collected after written informed consent. They were contacted telephonically to enquire about the adverse events. Data were entered in Microsoft Excel and analyzed using SPSS Version 23 to describe percentages and proportions. **Results:** The median age of 2532 participants was 31 (IQR 25-39) years and 60.4% were males. Minor adverse events were seen among 29.4% participants. Most common symptoms with first dose were fever, vaccination site tenderness, myalgia and headache, and with second dose were fever, myalgia, headache, and vaccination site tenderness. No severe adverse events were reported in our study. The adverse events were seen more among females ($P < 0.05$) and with the first dose ($P < 0.05$). **Conclusion:** Most common adverse events were similar to symptoms suggested by the vaccine manufacturers with fever being the most common one. A follow-up after a longer lag time may be recommended to enquire whether the vaccinees developed serious adverse events.

Keywords: Adverse events, COVID-19, Sputnik V, vaccination

Introduction

Coronavirus which causes COVID-19 infection has a dynamic nature and mutates frequently. Currently, there are 5 variants of concern (VOC) recognized by the World Health Organization (WHO), the latest being the Delta and Omicron variants.[1] In this scenario, the only best hope is vaccination against the disease. India launched its vaccination campaign on January 2021 in a 3-phased manner starting with Covishield. Currently, 12 vaccines are approved for use and 16 vaccines are undergoing clinical trials in India.[2] As of September 14, 2022, according to the COWIN portal (official website of the Government of India for vaccination against COVID-19), 94.56 crore beneficiaries in India and 5.50 crore beneficiaries in Karnataka have received both the doses of COVID-19 vaccine.[3]

The Sputnik V vaccine, also known as "Gam-COVID-Vac," was developed in Russia at The Gamaleya National Research Center of Epidemiology and Microbiology.[4] Sputnik V has an efficacy of 91.6% based on a study conducted among 19,866 volunteers.[5] It is a heterologous recombinant adenovirus using adenovirus 26 (Ad26) and adenovirus 5 (Ad5) as vectors for the expression of the SARS-CoV-2 spike protein in the two consecutive doses given to beneficiaries, respectively. It is given at a dose of 0.5ml each via intramuscular route in the upper third of the deltoid muscle. The phase 3 trial by the parent institute recruited 21977 participants and randomly assigned to vaccine group (n = 16,501) or the placebo group (n = 5476). Of them, 94% of volunteers complained of minor side-effects

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like flu-like syndromes, injection site reactions, headache, and asthenia.[5] These symptoms were similar to those developed after vaccination with Covishield and Covaxin. Seventy episodes of severe adverse events (SAE) were reported from the same trial but the side effects were decided to be not related to the vaccine by an Independent Data Monitoring Committee. In the Indian version of the clinical trial conducted, it was reported that out of 1500 volunteers recruited, 33.1% reported 1,784 adverse events but there were no SAE.[6] The safety of vaccines and the consecutive side effects have been studied in controlled settings by researchers. Our objectives were to document adverse events following administration of Sputnik V vaccine and examine the factors associated with adverse events among the vaccine beneficiaries from a teaching hospital of Mangalore, Karnataka.

Methodology

This was a cross-sectional study of all adult recipients (complete enumeration) of the Sputnik V vaccine from Yenepoya Medical College, Mangalore, situated in coastal Karnataka from September 6, 2021, to November 6, 2021. The vaccine recipients usually waited for 30 minutes post-vaccination to monitor for any immediate side effects as per the national guidelines for vaccination during the study period. During this waiting period, they were explained by postgraduate residents pursuing Community Medicine and trained medical interns, about the side effects of the vaccine as mentioned by the manufacturer in the information leaflet, in their native language (Kannada/Malayalam). Most of these vaccine recipients were from coastal Karnataka and northern part of Kerala. Informed written consent was obtained from those who were willing to be a part of the study. Any effects that the participants had during the post-vaccination observation period were recorded by the doctor in-charge of the vaccination session.

Information on socio-demographic data, contact details, and presence of any co-morbidity was collected. The beneficiaries were asked whether they developed any discomfort after receiving the vaccination and were asked to describe it in their own words. Later, these participants were contacted telephonically on the 7th day. A minimum of three telephonic calls were made before declaring the participant as non-respondent. The same protocol was followed when a participant took the second dose also. Any symptom reported by the participant that did not require hospitalization was considered as an adverse event (AE) and any symptom that needed medical intervention and hospitalization was considered as a serious adverse event (SAE). A dedicated phone number was provided to the participants to contact or message for any queries regarding the vaccine and to receive guidance on any side effects the participant may develop.

Data were entered in Microsoft Excel and analyzed using SPSS Version 23. Descriptive statistics were reported in the form of the mean (SD) and median (IQR) for continuous variables, depending on the distribution of the data, and categorical variables were presented as frequency (proportions). Exposure variables considered were age, gender, presence of comorbidities, and the dose of vaccine. Statistical significance was considered when the *P* value was less than 0.05.

Ethics approval was obtained from the institutional ethics committee (Protocol number: YEC2/887) of Yenepoya Medical College, Mangalore, on 12 August 2021. CTRI registration (CTRI/2021/09/036228) was obtained on September 3, 2021 before starting the study.

Results

A total of 3110 vaccine beneficiaries were approached to be part of the study. Of the 3099 participants who consented, 2532 (81.7%) could be contacted telephonically and were finally enrolled. Of the 1553 participants who took the first dose, 1237 (79.7%) responded, and of the 1546 participants who received the second dose, 1295 (83.8%) responded to the telephonic call.

The median (IQR) age of participants was 31 (25-39) years. The youngest was 18 years and the oldest participant was 84 years age. Most participants were males (1701/2532, 67.1%). A total of 99 (3.9%) participants reported of co-morbidities; 89 (3.5%) among these had diabetes mellitus, 23 (0.9%) had hypertension, 12 (0.5%) were with other co-morbidities (hypothyroidism, dyslipidemia, bronchial asthma). No adverse events were reported among any of our participants within 30 minutes of receiving both doses of the Sputnik V vaccine. Symptoms suggestive of adverse events were reported by 29.4% (745/2532) participants of which 450 (36.4%) was seen among those who received the first dose and 295 (22.8%) who received the second dose [Table 1] when they were contacted on the 7th day post-vaccination. All of them were considered as mild symptoms. No SAE were reported in our study. Of these who experienced an adverse event, 351 (75.7%) took some form of oral medication for symptomatic relief. Female gender and the first dose of the vaccine were associated with higher adverse events ($P < 0.05$) [Table 2].

Discussion

This is one of the first few studies from India that has looked into adverse effects of Sputnik V vaccine in India after its launch. A large sample size and a good response rate of the participants are strengths of this study. The telephonic interviews were conducted by doctors who were well versed with the symptoms that may appear after taking the vaccine.

The study revealed that three out of every ten participants complained of adverse effects following Sputnik V vaccination. This proportion was much more than the studies done from Iran and Argentina, which included only healthcare workers.[7,8] Our study participants reported no SAE, similar to studies conducted in Iran, Italy, and Russia.[5,9,10] A follow-up contact

Table 1: Symptoms suggestive of adverse events among participants who received first or second dose of Sputnik V vaccine at a tertiary medical college in coastal Karnataka, India, 2021. (*n*=2532)

Symptom suggestive of adverse event	Total beneficiaries (2532)	Dose 1 beneficiaries (1237)	Dose 2 beneficiaries (1295)
Any symptom*	745 (29.4)	450 (36.4)	295 (22.8)
Fever	450 (17.8)	282 (22.8)	168 (13)
Myalgia	154 (6.1)	86 (7)	68 (5.3)
Vaccination site tenderness	147 (5.8)	105 (8.5)	42 (3.2)
Headache	124 (4.9)	75 (3.8)	49 (4.9)
Asthenia	37 (1.5)	23 (1.9)	14 (1.1)
Nasopharyngeal symptoms	39 (1.5)	16 (1.2)	25 (1.9)
Arthralgia and pain in extremities	19 (0.8)	13 (1.1)	6 (0.5)
Cough	16 (0.6)	5 (0.4)	11 (0.8)
Dizziness	17 (0.7)	10 (0.8)	7 (0.5)
Increased temperature at vaccination site	14 (0.6)	7 (0.6)	7 (0.5)
Nausea and vomiting	13 (0.5)	6 (0.5)	7 (0.6)
Decreased appetite	5 (0.2)	1 (0.1)	4 (0.3)
Pruritis	2 (0.1)	0	2 (0.2)

Figures within brackets indicate percentages. *The sum total of each column is more than the individual symptoms put together as an individual would have experienced more than one symptom

Table 2: Comparison of presence of symptoms with sociodemographic and clinical variables among participants who received first or second dose of Sputnik V vaccine at a tertiary medical college in coastal Karnataka, India, 2021. (*n*=2532)

Variable	Category	Presence of symptoms *n* (%)	χ^2	*P*
Age	≤ 31 years**	400 (30.1)	0.654	0.419
	> 31 years	345 (28.7)		
Gender	Male	464 (27.3)	11.487	0.001*
	Female	281 (33.8)		
Comorbidities	Present	37 (37.4)	3.136	0.077
	Absent	708 (29.1)		
Dose	1st dose	450 (36.4)	56.338	<0.001*
	2nd dose	295 (22.8)		

* Statistically significant, **Median age of participants was 31 years

after a longer lag time may be recommended to gain knowledge on whether the vaccine recipients developed any serious adverse events.

Fever was the common side effect seen in our study with either of the doses. This was different from other studies done in Argentina, Iran, Italy, or Russia, where the most common event reported was vaccination site pain or tenderness. This was the third most common adverse event in our study.[7-9,11] The population included in our study may not have perceived this as an important side effect or their pain threshold would be higher. The most common symptoms, other than fever were myalgia, vaccination site tenderness or pain, headache, asthenia, and nasopharyngeal symptoms. These were similar to studies from Iran, Italy, and also from Russia during the phase 1/2 trial related to the vaccine, but not in the same order or proportion of participants reporting them.[7-9] In a study documenting SAE following Covishield or Covaxin, the most common symptoms were feeling generally unwell, headache, fever, fatigue, and myalgia.[12] These symptoms were similar to those from our study, although the proportions were different.

We did not find any association of the adverse events with the age categories. A study conducted by Jarynowski showed that the symptoms decreased with age and in the study by Pagotto *et al*.,[7] symptoms were reported more by participants who were 55 years or younger.[8,9,11] Participants who were younger than 40 years reported higher symptoms after COVID-19 vaccination in Iran.[10] A study by Kamal *et al*.[13] in India, reported that symptoms after Covishield or Covaxin were seen with participants who were more than 50 years of age.

Women seemed to be developed more symptoms similar to the findings from the studies by Pagotto *et al*.,[7] Montalti *et al*.,[9] and Jarynowski *et al*.[11] The study by Zare *et al*.,[10] comparing adverse events after taking either Covishield, Sputnik V, or Covaxin also showed that females reported more symptoms and it was more when they have received Sputnik V vaccination, while a study by Kamal *et al*.[13] shows that males reported more symptoms after vaccination with Covishield or Covaxin. The participants with comorbidities reported having more side effects in our study which is, similar to studies by Montalti *et al*.[9] and Jarynowski *et al*.[11] The symptoms were higher after receiving the first dose, compared to the second dose which is similar to the study from Argentina.[7] This significance may be due to the fact that those who received vaccine for the first-time reported symptoms more.

The National Technical Advisory Group on Immunization (NTAGI) in India has recommended that Sputnik Light which contains the Ad26 can be taken as precautionary dose starting from May 2022.[14] Knowing the adverse events will help participants make informed decisions to receive the vaccine. An important limitation of our study is that there might have under-reporting as the participants were contacted telephonically. The non-response rate is near 20% as a result

of which some adverse events especially SAE may have been missed. The study takes into account only beneficiaries from a specific population; hence, the results may not be generalizable.

Conclusion

This study revealed that the most common adverse event following Sputnik V administration was fever in general and also with either of the first or second doses. The adverse events were similar to symptoms suggested by the vaccine manufacturers. Adverse events were seen more among females and with the first dose.

Acknowledgement

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Consent to participate

Participants were explained the side effects of the vaccine as mentioned by the manufacturer in the information leaflet, in their native language. Informed written consent was obtained from those who were willing to be a part of the study.

Ethics approval

Ethics approval was obtained from the institutional ethics committee (Protocol number: YEC2/887) of Yenepoya Medical College, Mangalore, on 12 August 2021.

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Conflicts of interest

There are no conflicts of interest.

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