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Adverse Events Following Immunization of COVID-19 Vaccines: A Tertiary Care Hospital-Based Study from South Indian Population

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ABSTRACT

Background : Huge efforts have been made for vaccine research and administration in light of the public health measures implemented for the COVID-19 pandemic. Safety information following vaccination is not available due to the vaccine's recent development within in shorter duration. To allay concerns about adverse effects from vaccination, evidenced based information on immunisation must be continuously added. **Methods** : This cross sectional study was carried out in COVID-19 vaccine beneficiaries (Covishield, Covaxin, Sputnik-V) received two doses at Sri Ramachandra Hospital, Porur, Chennai, between September 2021 to March 2022. Relevant data was collected in a structured data collection form through telephonic interview. Results were retrieved and analysed. A simple descriptive statistical analysis was used to draw the results and expressed in percentage. **Results:** A total of 751 participants responded to the interview out of 803. Among them 127 (52%), 244 (70%) and 97 (60%) for Sputnik-V, Covishield and Covaxin. 468 (62.3%; range 18-60 years) observed with at least one adverse effect. 82.3% (*n*=385) of respondents reported very common adverse events, followed by 13.5% (*n*=63) common, 3.8% (*n*=18) uncommon, and 0.4% (*n*=2) unusual adverse events following immunization was observed and last for less than 72 hours. 70.5% used medication to treat AEFI. **Conclusion:** No severe or fatal adverse events were observed which lead to hospitalization hence all the 3 vaccines are safe. This study helps to build trust and confidence among the eligible beneficiaries so as to extend the benefits of vaccinations to control the current pandemic situation.

Keywords: Vaccine beneficiaries, Covishield, Covaxin, Sputnik–V.

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INTRODUCTION

The global pandemic known as the coronavirus disease of 2019 (COVID-19), a communicable disease has spread rapidly throughout the worldwide,[1] infected 460 million population and taking the lives of 6 million population by March 2022. As of March 2022, 43 million populations were affected and 0.52 million died with COVID-19 with a recovery rate of 98.76%.[2] As a new pandemic emerged with a new infection, no specific treatment available for COVID-19, avoiding COVID-19 virus exposure is the only method to combat this dangerous pandemic. Preventive measures like COVID-19 appropriate behaviour followed by vaccination are the mainstay of protection. Huge efforts have been made for vaccine research and administration considering the public health measures implemented for the pandemic.[3-5] In India, the Drug Control General of India (DCGI) have authorised the manufacture of many vaccines, including Covishield, Covaxin, Sputnik-V and Johnson & Johnson.[6,7]

The first phase of the initiative started on January 16, 2021 aims to immunise frontline workers and healthcare professionals. People with comorbidities who are 45 years old or more and older are eligible to obtain the COVID-19 vaccine in the second phase. Later (May, 2021), vaccine drive was extended to the adults' 18-44-years age group.[8] As end of March 2022, 1840 million vaccine doses have been administered national wide in India.[9] The number of daily cases decreased with excellent preventative measures and a vaccination campaign after the Omicron strain surged in India and throughout the world. Booster vaccination is necessary to stop further outbreaks of COVID-19.[2] Still there is a growing concern about vaccination side effects with increased booster dose administration. This would lead to reluctance to take booster doses, which would lead to a failure of 100% effectiveness in controlling the current pandemic. Limited research on vaccine

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safety may result from misperceptions of side effects and lack of knowledge about vaccine safety.

A few studies have reported adverse effects following immunisation (AEFI) of COVID-19 vaccines for Sputnik-V,[10] Covishield [11], and Covaxin.[12] There were no studies from the south Indian population explained the AEFI of these three vaccines. More information about AEFI should be regularly added to help allay worries about vaccine side effects. In this respect, the current investigation initiated with an objective to provide an evidence-based awareness on AEFI to COVID-19 vaccinations (Sputnik-V, Covaxin and Covishield), extending the evidence for more recent vaccines whose AEFI has gained less literature support.

MATERIALS AND METHODS

Study Design and Setting

This cross-sectional study was conducted using information gathered from vaccine recipients at Sri Ramachandra Medical College & Research Center, a tertiary care facility in South India, between November 2021 and April 2022. The protocol [CSP/21/NOV/102/590] was reviewed and approved by the institutional ethics committee. COVID-19 vaccines selected for the study were Covishield, Covaxin, and Sputnik-V. The ability to participate in a telephone interview, being older than 18 for both genders, including pregnant and nursing women, and having had two doses of the COVID-19 vaccination were prerequisites for inclusion criteria. Participants who had received one dose of any vaccination or other immunisation in addition to the research vaccines met the exclusion criteria, as vaccinations for children under the age of 18 were not permitted as of the study's start date.

Questionnaire Methodology

Participants in the study were questioned over the phone about the adverse effects of their vaccinations. The research team was instructed to collect data using a structured data collection form (Annexure 1). This structured data form includes all pertinent information on the study's goal, including gender, age, medical and medication histories, prior history of COVID-19 infection, a kind of vaccine, adverse reactions from immunisation, and management measures employed.

Questions on Adverse Events

Beneficiaries of both doses of the vaccination provided information on the type of vaccine administered and any adverse events (AEs) indicated in the form. For all three types of vaccines, the European Medicines Agency[13] categorised adverse events (AEs) as very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), and rare (≥1/10,000 to <1/1000). Pain at the injection site, fever, body ache, headaches, and fatigue were all very common side effects. Joint pain and swelling/redness at the injection site are common side effects. The uncommon events were injection-related rashes, diarrhoea, nausea, dizziness, and vomiting, whereas the rare events included shortness of breath. The form contained additional information such as spontaneous reports of unlisted events for the doses, the onset and resolution of each AE for each dose, medication used for treating any symptom/sign, and COVID-19 infection prior and after immunisation.

Statistics

The study was aimed to assess the qualitative variables for the AEs followed by immunisation; hence, the outcome measures in this study were expressed as number percentages. The association between demographic variables to adverse events was determined using the chi-square test. All the results were calculated using the Graph pad prism software version 5 and statistical significant was set at $p < 0.05$ for group differences.

RESULTS

Study Sample

This study observed that a total of *n*=803 vaccine beneficiaries, although 52 (6.5%) subjects were excluded because had not responded to the telephonic interview. The 751 remaining subjects were responded to a telephonic interview (a response rate 93.5%). 32.2% (*n*=242), 46.2% (*n*=347), and 21.5% (*n*= 162) received Sputnik-V, Covishield and Covaxin vaccine respectively. The enrolled subjects were between the ages 45.3±15 years (median 62 years; range 18 – 86 years). Of these 361 (48%) were females, and 390 (52%) were males. 62% (*n*=469) of vaccine beneficiaries were from the age group of 20-40 years, followed by 22.5% at age 46-60 years (*n*=169) and <20 years (7.4%; *n*=56).

162 (21.6%) participants had a confirmed COVID-19 infection before the immunisation, and no participant had severe disease or required hospitalisation. Despite the immunisation, 2% (*n*=1), 23% (*n*=21) and 5% (*n*=2) of subjects were noticed with COVID-19 infection for Sputnik-V, Covishield and Covaxin beneficiaries, respectively. (Table 1)

Vaccine related adverse events following immunisation

468(62.3%; range 18-60 years) individuals were reported at least one adverse event following immunization, most frequently by females n=256 (55%). 127 (52%), 244 (70%) and 97 (60%) for Sputnik-V, Covishield and Covaxin respectively. Covishield (p=0.037) and Covaxin (p=0.019) vaccinations had a marginally significant difference in the experience of adverse effects for both males and females, the exception of Sputnik-V (*p*=0.115).

Following immunization, 82.3% (*n*=385) of respondents reported very common adverse events, followed by 13.5% (*n*=63) common,

Table 1: Baseline characteristics of the study population.

Parameter		Number (Percentage)					
Total vaccine beneficiaries at study centre		803 (100)					
Responders to study		751 (93.5)					
Type of vaccine							
Sputnik-V		242 (32.2)					
Covishield		347 (46.2)					
Covaxin		162 (21.5)					
Gender distribution							
Sputnik-V	Male	150 (61.98)					
	Female	92 (38.02)					
Covishield	Male	154 (44.38)					
	Female	193 (55.62)					
Covaxin	Male	86 (53.09)					
	Female	76 (46.91)					
Age group (in years)		**Sputnik-V**		**Covishiled**		**Covaxin**	
		Male	**Female**	**Male**	**Female**	**Male**	**Female**
≤ 20		04 (2.7)	02 (2.17)	09 (5.84)	18 (9.33)	07 (8.14)	16 (21.05)
20-40		91 (60.66)	59 (64.14)	100 (64.94)	136 (70.46)	47 (54.65)	36 (47.37)
40-60		40 (26.66)	20 (21.73)	35 (22.73)	34 (17.62)	20 (23.26)	20 (26.32)
60-80		13 (8.66)	11 (11.96)	08 (5.19)	04 (2.07)	12 (13.95)	04 (5.26)
≥ 80		02 (1.32)	0	02 (1.3)	01 (0.52)	0	0
P-value		0.575		0.807		0.851	
Prevalence of COVID-19	Before	35 (23.33)	21 (22.83)	40 (25.97)	31 (16.06)	30 (34.88)	05 (6.58)
	After	0	01 (1.09)	10 (6.49)	11 (5.97)	0	02 (2063)
P-value for COVID-19 infection before and after immunization.		0.169		0.125		0.44	
Adverse effects followed by immunization.		72 (48)	55 (59.78)	96 (62.34)	148 (76.68)	44 (51.16)	53 (69.74)
P-value		0.115		0.037*		0.019*	

*Significant difference was observed between male and female for the adverse events after immunization with Covishield and Covaxin.

3.8% (*n*=18) uncommon, and 0.4% (*n*=2) unusual adverse events. The majority of vaccine recipients were seen to experience at least two adverse reactions after receiving the COVID-19 vaccination. Three women participants of reproductive age were reported delayed in menstruation after vaccination with Covishield, and three among them one is athlete reported fatigue and tiredness after two doses of Sputnik-V. No Serious adverse events (or) fatal events were reported in all three vaccines.

Most subjects (55.7%; *n*=418) experienced adverse effects at the injection site that were classified as very common, while 4.79% (*n*=36) and 0.13% (*n*=01) reported common and rare events respectively. Sputnik-V (*p*=0.39), Covishield (*p*=0.28), and Covaxin (*p*=0.24) vaccinations did not significantly differ between males and females in terms of inject site adverse effects. (Table 2)

Onset, duration, and work inconvenience of adverse events with Covid-19 immunisation.

Sputnik-V vaccine beneficiaries 47.24% (*n*=60) experienced adverse effects 2-4 hours after vaccination, whereas Covishield (53.69%; *n*=131) and Covaxin (26.80; *n*=26) experienced adverse events after 24 hours vaccination. For Sputnik-V, Covishield, and Covaxin, respectively, 60.63% (*n*=77), 57.79% (*n*=141), and 65.98% (*n*=64) of adverse events were cleared after 24-48 hours. After 72 h for all immunisations, nearly all the subjects had

Table 2: Adverse events following immunization.

Adverse Events		Sputnik-V (*n*=242)		Covishield (*n*=347)		Covaxin (*n*=162)	
		No. of Participants	No. of Events	No. of Participants	No. of Events	No. of Participants	No. of Events
Total number of participants experiences the event.		127 (52%)	942	244 (70%)	1455	97 (60%)	503
2 Symptoms		43(11%)	129	88(11%)	136	33(12%)	83
>2 Symptoms		33(9%)	320	97(12%)	150	34(12%)	73
Very common	Fever	88(23%)	200	222(27%)	580	60(22%)	130
	Body Pain	40(11%)	90	105(13%)	180	26(9%)	60
	Headache	35(9%)	60	66(8%)	130	16(6%)	32
	Tiredness	64(17%)	88	146(18%)	156	54(19%)	90
Common	Joint Pain	14(3.7%)	50	43(5%)	87	8(3%)	20
Uncommon	Diarrhoea	0(0%)	0	2(5%)	6	0(0%)	0
	Nausea	0(0%)	0	4(0.49%)	10	4(1.4%)	10
	Dizziness	0(0%)	0	3(0.36%)	5	1(0.3%)	5
	Vomiting	0(0%)	0	4(0.49%)	7	0(0%)	0
Rare	Shortness Of Breath	0(0%)	0	2(0.24%)	3	0(0%)	0
Unexpected	Delay in Menstruation	0(0%)	0	3(0.36%)	5	0(0%)	0
	Fatigue and Tiredness After Two Doses	3(0.7%)	5	0(0%)	0	0(0%)	0
Symptoms at injection site							
Total number of participants experiences the event		138(57%)	153	213(61%)	244	106 (65%)	127
Very common	Local Pain	136(35%)	150	182(22%)	210	102(37%)	115
Common	Swelling	1(0.2%)	2	23(2.8%)	25	3(1%)	10
	Redness	1(0.2%)	1	7(0.8%)	7	1(0.3%)	2
Rare	Rashes	0(0%)	0	1(0.1%)	2	0(0%)	0
Significance between gender		*p*=0.39¶		*p*=0.28¶		*p*=0.24¶	

¶- No significant difference was observed between male and female for the adverse events at injection site with all three vaccines.

recovered from their AEFI. Sputnik-V (P-0.666; 0.489), Covishield (P-0.594; 0.586), and Covaxin (P-0.304; 0.797) adverse event initiation and resolution were not significantly different between males and females. A difficulty in working was noted in 24.3% (*n*=183) of the population, and a medication was administered to treat the AEFI in 70.5% (*n*=530) of the cases (Table 3).

DISCUSSION

Since the earlier stage of the development of vaccination against COVID-19, concerns and anxiety have been observed in the population worldwide over the adverse events and risks related to these vaccines. Thus in present study, post vaccination adverse events are monitored and it is important to inform the public and policymakers about the safety and possible severe adverse reactions of the vaccine.[14] In this cross-sectional study, responses from vaccine beneficiaries for all three vaccines were found to be different, i.e., 32.2%, 46.2%, and 21.5% for Sputnik-V, Covishield & Covaxin respectively. Two reasons can be predicted for this percentage variation among vaccine beneficiaries: one is the time variation in their launch to the market in India. Second is the Government made the availability of Covishield for free cost by conducting vaccine drive programmes in public to combat with the COVID-19 pandemic. No significant age group differentiation was found between male and female (p>0.05) among all types of immunisation. The gender distribution of the present data showed that most of the beneficiaries were males in Sputnik (62%), followed by females in Covishield (56%) and male in Covaxin (53%).The highest percentage of vaccine recipients was found to be in the age group of 20-40 years. This may be because most of the frontline workers (healthcare professionals of the organization) and students at the study center are under

Table 3: Onset, duration and work inconvenience for adverse events with Covid-19 immunization.

Onset of symptoms									
Time in Hours	Sputnik-V *n*=127 (52%)			Covishield *n*=244 (70%)			Covaxin *n*=97 (60%)		
	Male	Female	p – 0.666	Male	Female	p – 0.594	Male	Female	p – 0.304
< 2	1 (0.7%)	0		2 (0.5%)	5 (2.04%)		2 (2%)	1 (1%)	
2-4	34 (26.7%)	26 (20.4%)		2 (0.5%)	13 (5.3%)		8 (8.16%)	4 (4.12%)	
4-8	18 (14.17%)	20 (15.7%)		17 (6.9%)	18 (7.3%)		10 (10.3%)	15 (15.4%)	
8-12	3 (2.3%)	0		17 (6.9%)	13 (5.3%)		3 (3%)	14 (14.4%)	
12-24	11 (8.6%)	4 (3.1%)		5 (2.04%)	21 (8.60%)		6 (6.18%)	8 (8.16%)	
≥ 24	6 (4.7%)	5 (3.9%)		57 (23.3 %)	74 (30.3%)		10 (10.3%)	16 (16.4%)	
Duration of symptoms									
< 8	2 (1.5%)	0	p – 0.489	0	0	p – 0.586	0	0	p – 0.797
8-24	1 (0.7%)	3 (2.3%)		14 (5.7%)	23 (9.4%)		10 (10.3%)	7 (7.2%)	
24-48	43 (33.8%)	34 (26.7%)		57 (23.3%)	84 (34.4%)		27 (27.8%)	37 (38%)	
48-72	48 (37.7%)	10 (7.8%)		23 (9.4%)	36 (14.7%)		3 (3%)	8 (8.16%)	
≥72	5 (3.9%)	8 (6.2%)		5 (2.04%)	7 (2.8%)		3 (3%)	2 (2%)	

Prevalence of Inconvenience to work & medication taken by vaccine beneficiaries

Assessment		Total *n*=751 (%)	Types of vaccine								
			Sputnik-V (*n*=242)			Covishield (*n*=347)			Covaxin (*n*=162)		
			Male	Female		Male	Female		Male	Female	
Inconvenience to work	Yes	183 (24.3%)	14 (5.7%)	7 (2.8%)	p – 0.413	49 (14.1%)	78 (22.4%)	p – 0.288	19 (11.7%)	16 (9.8%)	p – 0.242
	No	568 (75.6%)	136 (56%)	85 (35%)		105 (30%)	115 (33%)		67 (41.3%)	60 (37%)	
Medication taken	Yes	530 (70.5%)	73 (30%)	50 (20.6%)	p – 0.121	124 (35.7%)	164 (47.2%)	p – 0.515	60 (37%)	59 (36.4%)	p – 0.374
	No	220 (29.2%)	76 (31.4%)	42 (17.3%)		30 (8.6%)	29 (8.3%)		24 (14.8%)	19 (11.7%)	

the age of 60 and the majority of the information reported at a young age because of their responses. These results were in line with the results reported by the author Zare *et al.*, (2021)[4] where in the percentage of vaccine beneficiaries were (69%) under the age of ≤ 40 years. Of all Covid-19 infected subjects among vaccine beneficiaries, male sex was predominant; this result is not surprising given the earlier literature[15] and statistics of Covid-19 infection by government agencies such as ICMR that have a higher infection rate in men.

As per the fact sheets cited in published literature and government agencies,[16] most of the population have reported a myth of getting infected with COVID-19 infection after immunisation and to explain the fact, limited literature on vaccine safety is available to date. Therefore, the current study focused on pre- and post-COVID-19 infection rates of immunisation. The results of this study strengthen the fact that COVID-19 immunization is less likely to cause COVID-19 infection, as evidenced by the negligible percentage of post infection in vaccine beneficiaries and there is no significance (P>0.05) observed in COVID-19 infection in pre and post immunisation for all vaccines.

Considering the age of the vaccine recipients in this study, there was a relatively large number of adverse events followed by immunisation (AEFI) in those under 40 years of age. However, based on the findings of this study, it is impossible to confirm that AEFI is higher in young people than in older people. One possible factor to be considered is that at the beginning of the nationwide vaccination programme for COVID-19, the initial phase was targeted at frontline workers across the country and then followed for individuals over 45 years of age. Many older people received their vaccine before conducting the study began

and younger ones started getting vaccinated. This study limits its data collection in an institution where most of the vaccine beneficiaries were under 60 years of age, and their relative responses may also be higher to estimate the number of reported events is higher at younger age groups.

Overall, 62% of subjects reported having at least one symptom for the vaccine they received. In this study, the percentage of AEFI was slightly higher in females, i.e., 55%, where in a cross-sectional study by Iran by Zare *et al.,* 2021[4] it was 90.6% and it was 72.6% in females reported by Ripabelli *et al.,* 2021.[17]

Of all study subjects, 52%, 70% and 60% were reported with AEFI for Sputnik, Covishield and Covaxin respectively. Regardless of the type of vaccine received by study subjects, these side effects were categorised as very common, common, uncommon, and rare for all three vaccines. The frequency of the important side effects of very common and common for Sputnik-V as well as for Covishield is observed to be similar and as follows: Fever > Tiredness > Body pain > Headache > Joint pain. The frequency of the important side effects very common and common for Covaxin is as follows: Fever > Tiredness > Headache > Body pain > Joint pain. These results are quite contrast to the results reported by Zare *et al.,* (2021)[4,] where fatigue was the most frequent symptom observed in vaccine beneficiaries with all three vaccines. Very few observations from the results of side effects with Covishield were reported with uncommon symptoms and the frequency is as follows: Nausea > Vomiting> Dizziness > Diarrhoea. A negligible percentage was observed with menstrual delay for Covishield and fatigue for Sputnik-V, as today there was no scientific explanation available to debate on menstrual delay in women with vaccination. Further in-depth clinical research may require to prove the same. Fatigue with Sputnik-V in 3 patients was due to an unrevealed or non-symptomatic attack of Covid infection earlier to the vaccination. Although, the main common side effect in the three vaccine groups was "injection site pain", the prevalence and frequency of the other side effects were reported differently in these three groups. The prevalence of local side effects (injection site pain) has <10% variation for the vaccines. The results of injection site symptoms were similar to the results reported by the different studies Zare *et al.,* (2021),[4] Kamal *et al.,* (2021)[18] and Ripabelli *et al., (*2021).[17] The onset of post vaccination symptoms of the study beneficiaries was revealed that the highest percentage, i.e., (46%) for Sputnik-V and Covishield (52%) and Covaxin (31%) were observed at greater than 24 h. Also, the duration of post vaccination symptoms of the study revealed that the highest percent was 63%, 57% & 69% of subjects experienced these symptoms for 24-48 hours after administration for Sputnik-V, Covishield, Covaxin respectively. These results are contrast to the data reported by Ripabelli *et al.,* (2021),[17] where the data showed that the duration of symptoms was high during 4 to 24 h.. The prevalence of inconvenience to work after immunisation was only about 19% and the rest of 81% did not find any inconvenience to work after immunisation. Also, 66% of the vaccine beneficiaries had taken the medication following immunisation. There was no significant difference found between male and females in the onset and duration of symptoms and for inconvenience and medication use for AEFIS.

LIMITATION

This study has some limitations. As the data collection relied solely on the input given by the subject through a telephonic interview, there might have been unmeasured factors that influence the percentage depicted in the results. This study, did not allow any inference of long-term events, and only short-term events were observed.

CONCLUSION

Findings of the study revealed, that adverse events were more frequently reported in individuals under 60 years of age, including both male and female. It generally lasted 1-2 days from the injection. No severe adverse events were observed, which may lead to hospitalisation and very commonly reported adverse events are fever, generalized body pain and headache that were mild and manageable with the medication. Hence, this study helps build trust and confidence among eligible beneficiaries and all 3 vaccines were found to be safe.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIAITONS

COVID-19: Corona Virus disease 2019 ;**AEFI:** Adverse effects following immunisation; **DCGI:** Drug Control General of India; ICMR: Indian council of medical research; **AE:** Adverse event

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