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Original Research Article

Adverse events with COVID-19 vaccination (precaution dose) among the elderly population aged 60 years and above in South India

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ABSTRACT

Background: India started administering the precaution dose or the Booster dose of COVID vaccine from 10 January 2022 to comorbid people aged 60 and above. To identify the adverse events with COVID-19 vaccination (precaution dose) among the elderly population aged 60 years and above. To determine the association between adverse reactions and sociodemographic factors, morbidity profile and previous history of COVID 19.
Methods: This cross-sectional study was undertaken at COVID- 19 vaccination centre, of SVIMS, Tirupati. AP from January 2022 to July 2022. Data was collected by interviewing the study subjects. Study respondents who received COVID-19 vaccine were observed for a period of 30 minutes and after 48 hours, study participants were contacted through telephone to find out any vaccine related adverse effects.
Results: Overall, 676 of 60 years or older received their precaution dose. Majority of the respondents were in 60-70 years age group (60.8%) males (n=397, 58.7%) were higher than females (n=279,41.3%). Out of 676, 34 (5.0 %) participants reported adverse effects after 1st or 2nd dose. With regard to precaution dose, only 43 (6.4%) reported adverse events within the 30 minutes of receiving COVID-19 vaccine. While 54 (8.0%) reported adverse events in last 48 hours after receiving COVID-19 vaccine (precaution dose). Spectrum of symptoms reported were fever, anxiety, dizziness/giddiness, body pains, headache, nausea, pain at injection site, pain in abdomen, swelling at injection site, rash.
Conclusions: Only 43 (6.4%) reported adverse events within the 30 minutes of receiving COVID-19 vaccine while 54 (8.0%) reported adverse events in last 48 hours after receiving COVID-19 vaccine(precaution dose).There were no reports of serious adverse effects..

Keywords: COVID-19 Vaccination, Precaution dose, Adverse Events Following Immunization, Elderly population

INTRODUCTION

COVID-19 pandemic broke out in December 2019 and spread across the world. The Government of India took proactive steps to respond to the pandemic and initiated the preparedness of the health systems to respond to all aspects of COVID-19 management.[1]

Over the years vaccines have provided highly cost-effective improvements to human health by reducing avoidable human suffering, costs of care and treatment, economic consequences of work i.e. lower productivity and loss of work.[2] The COVID-19 vaccination drive, the world's largest vaccination drive so far, was launched by the Hon'ble Prime Minister on 16th January 2021. The

Day 1 witnessed vaccination of the highest number of beneficiaries covered anywhere in the world on the first day 1.

The elderly population in India has steadily increased and has almost doubled in the past 20 years.[3] Increasing age is a significant risk factor associated with death because of COVID-19.[4] Elderly people are at a higher risk of COVID-19 infection due to their decreased immunity and body reserves, as well as multiple associated co-morbidities like diabetes, hypertension, chronic kidney disease and chronic obstructive pulmonary disease. Also, course of disease tends to be more severe in case of elderlies resulting in higher mortality.[5]

India will start administering the precaution dose or the Booster dose of COVID vaccine from 10 January to healthcare and frontline workers and comorbid people aged 60 and above in a bid to stymie the coronavirus spread driven by its Omicron variants.[6]

Adverse event following immunization is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. If not rapidly and effectively dealt with, can undermine confidence in a vaccine and ultimately have dramatic consequences for immunization coverage and disease incidence. Vaccine-associated adverse events may affect healthy individuals and should be promptly identified to allow additional research and appropriate action to take place. Vaccine-associated adverse events may affect healthy individuals and should be promptly identified to allow additional research and appropriate action to take place.[7]

Objectives

To identify the adverse events with COVID-19 vaccination (precaution dose) among the elderly population aged 60 years and above.

To determine the association between adverse reactions and sociodemographic factors, morbidity profile and previous history of COVID 19.

METHODS

This was a cross-sectional study undertaken at COVID-19 vaccination centre, SVIMS, Tirupati of Chittoor district of Andhra Pradesh state in South India, from January 2022 to July 2022.

Study population

The study population comprised of all the elderly persons aged 60 years and above who visits for COVID- 19 vaccination (Covaxin /Covishield) at SVIMS Vaccination Centre.

Sample size

All the eligible beneficiaries who visits vaccination Center during the study period were included in the study.

Inclusion criteria

Elderly persons aged more than 60 years and above. Subjects who were willing to participate.

Exclusion criteria

Those who get vaccine from other vaccination centres. Those with absolute contraindication for vaccine.

Data collection methods

Data was collected by interview technique using a pre-designed and pre-tested questionnaire. They were interviewed about their socio-demographic profile, any morbidity, any allergies, past history of COVID-19 and adverse effects following COVID-19 vaccination.

All the study respondents who received COVID-19 vaccine were observed for a period of 30 minutes in the observation room as per the guidelines of Government of India. After 48 hours, study respondent was contacted through telephone to find out any vaccine related adverse effects. Data was collected by the investigators along with the research team. All the investigators were trained in observing adverse events following vaccination and also were trained in collecting data.

Study instruments

Structured format

It was prepared and was used to collect data. It included socio-demographic details of the study participant like age, gender, educational level, occupation and place of residence, other information included were previous history of COVID-19 infection and history of hospitalization, history of quarantine for COVID-19, any morbidities, history of allergy to food, drugs and vaccines.

Ethical issues

Ethics approval was obtained from the Institutional Ethical Committee Informed consent was taken from the study respondents.

Statistical analysis

Data analysis was done using IBM Statistical Package for Social Science Statistics for Windows, Version 26.0. The proportion of AEFI reported was calculated. Chi-square test was applied to find out the association between outcome and predictor variables. A $p<0.05$ was considered significant.

RESULTS

Study participants were individuals 60 years or older who received the precaution dose (booster dose) of the COVID-19 vaccine during the COVID vaccination drive sessions (June 2021 to July 2022).

The data were obtained from a total of 676 individuals 60 years or older, who were enrolled for the precaution dose of Covishield vaccine during the vaccination drive, at SVIMS Vaccination centre from 10 January 2022 to July 2022.

Table 1 summarizes the basic characteristics of the study participants.

Table 1: Demographic details of the vaccine recipients (n=676).

Variable		Number	Percentage (%)
Locality	Rural	42	6.2
	Urban	634	93.8
Age group	60-70 years	411	60.8
	71-80 years	233	34.5
	>80 years	32	4.7
Gender	Female	279	41.3
	Male	397	58.7
Education	Illiterate	56	8.3
	Primary	76	11.2
	Secondary	200	29.6
	Graduate	149	22.0
	Post graduate	195	28.8
Working status	Still working	69	10.2
	Retired	422	62.4
	Home maker	185	27.4

Overall, 676 of 60 years or older received their precaution dose at vaccination center of tertiary health care hospital. Majority, 634 (93.8%) of the respondents were urban residents and only 42 (6.2%) were rural residents. Majority of them were aged 60-70 years,411 (60.8%), 233 (34.5%) were aged 71-80 years and more than 80 years were only 32 (4.7%).

In this study, males were higher 397 (58.7%) than females, 279 (41.3%). Regarding educational status, 56 (8.3%) were illiterates. Majority of the respondents were retired from their job, 422 (62.4%), 69 (10.2%) respondents were still working and 185 (27.4%) respondents were home makers.

As depicted in Table 2, 485 (71.7%) of the study respondents reported co-morbidities. Majority of the respondents i.e. 616 (91.1%) had no habits like smoking or alcoholism. Only 44 (6.5%) had habit of smoking and 16 (2.4%) had habit of drinking alcohol.

Table 2: Habits and comorbidity of vaccine recipients (n=676).

Variable		Number	Percentage (%)
Habits	Smoking (tobacco)	44	6.5
	Alcohol	16	2.4
	No habits	616	91.1
Comorbidity	Yes	485	71.7
	No	191	28.3

Table 3: History of COVID-19 among vaccine recipients and their family members (n=676).

Variable		Number	Percentage (%)
History of positive for COVID 19	Yes	202	29.9
	No	474	70.1
Any family member positive for COVID 19	Yes	233	34.5
	No	443	65.5
History of quarantine for COVID 19	Yes	192	28.4
	No	484	71.6

Table 4: History of allergies among vaccine recipients (n=676).

Variable		Number	Percentage (%)
History of allergy to any food	Yes	10	1.5
	No	666	98.5
History of allergy to any medicines	Yes	23	3.4
	No	653	96.6
History of allergy to any vaccines	Yes	2	0.3
	No	642	99.7

Table 5: Adverse events after 1st and 2nd dose of Covid-19 vaccine among vaccine recipients (n=676).

Variable		Number	Percentage (%)
History of adverse events after 1st or 2nd dose	Yes	34	5.0
	No	642	95.0
Adverse events within 30 minutes of receiving precaution dose.	Yes	43	6.4
	No	633	93.6
Adverse events in past 48 hours of receiving precaution dose.	Yes	54	8.0
	No	622	92.0

As depicted in Table 3, 202 (29.9%) of the study the respondents had suffered COVID-19 either during first wave or second wave of COVID-19 pandemic. Out of total 676, 233 (34.5%) respondents reported that some of

their family members had suffered due to COVID-19 disease and 192 (28.4%) reported that, they were quarantined during COVID-19 pandemic.

As depicted in Table 4, when asked about any allergies to food, medicines and vaccines, 10 (1.5%) of the study respondents reported that they were allergic to food, 23 (3.4%) reported that they were allergic to certain medicines and only 2 (0.3%) reported that they were allergic to vaccines.

As depicted in Table 5, adverse events following immunization (AEFI) were assessed within 30 min of receiving vaccine in vaccination centre only, then within 2 day (48 hours) of receiving the vaccine.

As depicted in Table 5, Out of 676, 34 (5.0%) respondents reported that they experienced adverse effects after 1st or 2nd dose.

Table 6: Association between adverse events with in 30 min and in in past 48 hours with demographic, comorbidity, history of COVID and other allergies.

Variable		Adverse events with in 30 min (n=43)		P value Odds ratio (95% CI)	Adverse events in past 48 (n=54)		P value Odds ratio (95% CI)
		Yes	No		Yes	No	
		No (%)	No (%)		No (%)	No (%)	
Age group	60-70 years	28 (6.8)	383 (93.2)		40 (9.7)	371 (90.3)	
	71-80 years	13 (5.6)	220 (94.4)	0.82	12 (5.2)	221 (94.8)	0.11
	>80 years	2 (6.3)	30 (93.8)		2 (6.3)	30 (93.8)	
Gender	Male	23 (8.2)	256 (91.8)	0.09	24 (8.6)	255 (91.4)	0.62
	Female	20 (5.0)	377 (95.0)	1.69 (0.91-3.14)	30 (7.6)	367 (92.4)	1.15 (0.65-2.01)
Education	Illiterate	1 (1.8)	55 (98.2)		2 (3.6)	54 (96.4)	
	Primary	5 (6.6)	71 (93.4)		8 (10.5)	68 (89.5)	
	Secondary	13 (6.5)	187 (93.5)	0.50	18 (9.0)	182 (91.0)	0.31
	Graduate	8 (5.4)	141 (94.6)		15 (10.1)	134 (89.9)	
	Post graduate	16 (8.2)	179 (91.8)		11 (5.6)	184 (94.4)	
Working status	Still working	4 (5.8)	65 (94.2)		7 (10.1)	62 (89.9)	
	Retired	24 (5.7)	398 (94.3)	0.52	29 (6.9)	393 (93.1)	0.38
	Home maker	15 (8.1)	170 (91.9)		18 (9.7)	167 (90.3)	
Locality	Rural	0 (0)	42 (100)	0.08	6 (14.3)	36 (85.7)	0.12
	Urban	43 (6.8)	591 (93.2)		48 (7.6)	586 (92.4)	
Habits	Smoking (Tobacco)	2 (4.5)	42 (95.5)		7 (15.9)	37 (84.1)	
	Alcohol	2 (12.5)	14 (87.5)	0.53	1 (6.3)	15 (93.8)	0.13
	No habits	39 (6.3)	577 (93.7)		46 (7.5)	570 (92.5)	
Comorbidity	Yes	32 (6.6)	453 (93.4)	0.68	43 (8.9)	442 (91.1)	0.18
	No	11 (5.8)	180 (94.2)	0.865 (0.427-1.753)	11 (5.8)	180 (94.2)	0.628 (0.317-1.246)
History of positive for COVID 19	Yes	15 (7.4)	187 (92.6)	0.459	13 (6.4)	189 (93.6)	0.331
	No	28 (5.9)	446 (94.1)	0.783 (0.409-1.499)	41 (8.6)	433 (91.4)	1.377 (0.721-2.629)
Any family member positive for COVID 19	Yes	15 (6.4)	218 (93.6)	0.953	20 (8.6)	213 (91.4)	0.679
	No	28 (6.3)	415 (93.7)	0.981 (0.513-10875)	34 (7.7)	409 (92.3)	0.885 (0.497-1.576)
History of quarantine for COVID 19	Yes	12 (6.3)	180 (93.8)	0.941 1.026	8 (4.2)	184 (95.8)	0.021 2.416
	No	31 (6.4)	453 (93.6)	(0.516-2.043)	46 (9.5)	438 (90.5)	(1.118-5.218)
History of allergy to food	Yes	0 (0)	10 (100)		1 (10)	9 (90)	0.813
	No	43 (6.5)	623 (93.5)	0.406	53 (8.0)	613 (92)	0.778 (0.097-6.260)
History of	Yes	1 (4.3)	22 (95.7)	0.687	1 (4.3)	22 (95.7)	0.512

Continued.

Variable		Adverse events with in 30 min (n=43)		P value Odds ratio	Adverse events in past 48 (n=54)		P value Odds ratio
allergy to any medicines	No	42 (6.4)	611 (93.6)	1.512 (0.199-11.495)	53 (8.1)	600 (91.9)	1.943 (0.257-14.702)
History of allergy to any vaccines	Yes	0 (0)	2 (100)	0.712	0 (0)	2 (100)	0.676
	No	43 (6.4)	631 (93.6)		54 (8)	620 (92)	
History of adverse events after 1st or 2nd dose	Yes	3 (8.8)	31 (91.2)	0.546 0.687 (0.201-2.343)	5 (14.7)	29 (85.3)	0.138 0.479 (0.178-1.293)
	No	40 (6.2)	602 (93.8)		49 (7.6)	593 (92.4)	

Table 7: Distribution of adverse events following immunization.

Type of adverse event	Within 30 min (n=43) N (%)	In past 48 hours (n=54) N (%)
Fever	4 (9.3)	25 (46.3)
Anxiety	5 (11.6)	0 (0)
Dizziness/giddiness	10 (23.2)	3 (5.5)
Body pains	6 (13.9)	18 (33.3)
Head ache	5 (11.6)	5 (9.3)
Nausea	2 (4.6)	0 (0)
Pain at injection site	5 (11.6)	20 (37.1)
Stomach pain	4 (9.3)	0 (0)
Swelling at injection site	1 (2.3)	15 (27.7)
Rash	0 (0)	1 (1.8)

With regard to precaution dose, only 43 (6.4%) reported adverse events within the 30 minutes of receiving COVID-19 vaccine. Majority of them, 633 (93.6%) did not report any adverse events following vaccination. While 54 (8.0%) reported adverse events in last 48 hours after receiving COVID-19 vaccine (precaution dose).

With regard to precaution dose, only 43 (6.4%) reported adverse events within the 30 minutes of receiving COVID-19 vaccine. Majority of them, 633 (93.6%) did not report any adverse events following vaccination. While 54 (8.0%) reported adverse events in last 48 hours after receiving COVID-19 vaccine (precaution dose).

As shown in Table 7, spectrum of symptoms reported within 30 min of vaccination and within 48 hour were fever, anxiety, dizziness/giddiness, body pains, headache, nausea, pain at injection site, pain in abdomen, swelling at injection site, rash.

DISCUSSION

Older adults are more likely to get very sick from COVID-19. Getting very sick means that older adults with COVID-19 might need hospitalization, intensive care, or a ventilator to help them breathe, or they might even die. The risk increases for people in their 50s and increases in 60s, 70s, and 80s.[8]

Present study was conducted at vaccination centre of tertiary health care center in Tirupati (Andhra Pradesh).We have investigated adverse events following immunization (AEFIs) associated with Precaution dose of COVID-19 vaccine among 60 years and older.

In present study, the total number of respondents were 676. The proportion of male respondents were more 58.7% than females 41.3%. Majority of them were aged 60-70 years (60.8%), 34.5% were aged 71-80 years, and more than 80 years were only 4.7%. Regarding educational status, 56 (8.3) were illiterates and majority of them had education up to secondary level (29.6%).

With regard to their occupation, 62.4% respondents were retired from their job while10.2% respondents were still working and 27.4% of them were home makers. Similarly in a study by Auster et al, the median age of respondents was 71 years (IQR, 66-75 years); 43.6% of respondents were aged 60 to 69 years; 44.5%, 70 to 79 years; and 12.0%, 80 years or older.[9] The proportion of female respondents were 45.3%.

Of the total respondents, 5.0% respondents reported that they experienced adverse effects after 1st or 2nd dose which were symptoms. With regard to precaution dose (booster dose), 6.4% reported adverse events within the 30 minutes of receiving COVID-19 vaccine while 8.0% reported adverse events in last 48 hours after receiving

COVID-19 vaccine (precaution dose). We found that overall common adverse events after the precaution dose (booster dose) of the COVID-19 vaccine (Covishield and Covaxin vaccine) were fever, myalgia, fatigue, giddiness, pain at injection site and swelling at injection site etc. Symptoms were mild in severity and non-serious type.

A study by Auster et al reported that among adults aged 60 years and older, the most common adverse events (AEs) following a third dose of the BNT162b2 COVID-19 vaccine were mild, including injection site pain, fatigue, and malaise.[9]

Choudhary et al study found that overall 97 (18.8%) recipients developed non-serious AEFI after the first dose and 2 (0.3%) after the second dose of vaccination.[10] Most of the adverse events were short-lived and reported in the first 24h of vaccination. Kundawar et al found that a greater number of participants experienced adverse events after the first dose compared to the second dose of the vaccine.[11] A study by Mahapatra S et al found in their study that short-term adverse events of the Covishield vaccine were moderate in frequency and mild in severity.[12] On the contrary to this, Kamal D et al found in their study two serious AEFI (altered sensorium) and 1020 non-serious AEFI were reported within 48 hours of first dose.[13] 220 non-serious AEFI were reported within 48 hours of second dose. Similarly in a study by Bhandari A et al found that for respondents in the age group 60-70 years, AEFI reported were 8.7% with the first dose and 6.4% with the second dose.[14] Arora G et al observed in their study, breakthrough infections in 7.91% (88/1112; 57.96% males and 42.04% females) with the older age group, 61 years and above.[15] In a survey done by Jayadevan R et al tiredness was the most common symptom (45%), followed by myalgia (44%), fever (34%) and headache (28%).[16] Local pain at the injection site was reported by 27% of the respondents. None of the symptoms were of serious nature or requiring hospitalization. Jayadevan R et al also reported that the chance of having symptoms decreased with advancing age.[16] There was no significant difference in the incidence of adverse effects between the first, second and precaution dose (booster dose) in present study and study by Auster O et al.[9]

In present study, 71.7%of the study respondents reported co-morbidities. The most common comorbidities found among vaccine recipients had diabetes and hypertension which are more prevalent in the older age group. In a study by Parida et al, revealed that only 5.8% of the study participants had any of the co-morbidities.[17] In this study, majority of the participants i.e. 616 (91.1%) had no habits like smoking or alcoholism. Only 6.5% had habit of smoking and 16 (2.4%) had habit of drinking alcohol.

In present study, 29.9% respondents reported past history of COVID-19 during first wave or second wave of pandemic. 34.5% respondents reported that some of their family members were positive for COVID-19 and 28.4% said they were quarantined during COVID-19 pandemic.

We found that the proportion of study respondents reported to have allergies to food, certain medicines and vaccines were 10 (1.5%), 23 (3.4%), 2 (0.3%) respectively. Parida et al, found only 1.4% participants had known allergy to any kind of food, drug, pollen, dust or other allergens.[17]

After evaluation of association of AEFI with socio-demographic variables, history of allergy, addictions like smoking and alcoholism, past history of Covid-19 and co-morbidity among respondents, we found that AEFI was more in 60-70 years aged both within 30 minutes (6.8%) and in within next 48 hours (9.7%) of vaccination.

In present study adverse effects was greater in 60-70 years aged respondents. Similar findings were reported by other studies.[9,14,17]

AEs was found to be greater (8.2%) among male respondents within 30 minutes of vaccination while among females respondents reported higher (7.6%) adverse effects within next 48 hours. Auster O et al study showed that proportion of female respondents who reported systemic AEs was greater than the proportion of male respondents. Similar findings were observed in other studies.[9,14,17]

Those who were retired from their work reported more adverse effects following vaccination both within 30 minutes and within next 48 hours (5.7%) and (6.9%) respectively. But it was not statistically significant.

Respondents with co-morbidity such as Diabetes and Hypertension were found to be have more adverse effects following vaccination both within 30 minutes and within next 48 hours (6.6%) and (8.9%) respectively. But it was not statistically significant. Parida SP et al reported in their study that individuals with any comorbidities were 2.08 times more likely to have AEFI than those having no comorbidity ($p<0.001$).[17]

In present study, AEs was not associated with the history of allergies among respondents but in a study byParida SP et al, AEFI was 2.39 times more reported among individuals with a history of allergic reaction than those with no previous history.[17] AEs within 30 minutes of vaccination are seen more in people who had a past history of Covid-19 infection (7.4%) while within next 48 hours are seen more in people with no past history of Covid-19 (8.6%).Similarly in a study by Parida SP et al, individuals having COVID-19 infection in the last 3 months and history of hospital admission in the last 3 months had 7.10 times more AEFI, but the difference was not significant statistically.[17]

Limitations of the study

This study only looked at adverse events till next 48 hours following vaccination. A longer follow-up was needed. Further studies to record long tern adverse effects is recommended.

CONCLUSION

Adverse events reported within the 30 minutes were 6.4% while within next 48 hrs after receiving COVID-19 vaccine (precaution dose) were 8.0%.Most of the adverse events were mild and short-lived. Adverse effects were greater in 60-70 years aged respondents with greater proportion among (8.2%) among male respondents within 30 minutes of vaccination while among female's respondents reported higher (7.6%) adverse effects within next 48 hrs. Respondents with co-morbidity were found to be have more adverse effects following vaccination both within 30 minutes and within next 48 hrs (6.6%) and (8.9%) respectively.

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