The safety profile of COVID-19 Vaccination among 1373 elderly population

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Abstract

Introduction: COVID-19 infection caused by the SARS COV-2 virus is one of the largest pandemics and has affected every nation worldwide. The introduction of different vaccines against COVID-19 infection has bought new hope in the fight against COVID-19, which would decrease the ongoing crisis. These vaccines were approved for emergency purposes, which had fewer clinical trials involving elderly populations. Hence, this study intends to know the safety profile of the COVID-19 vaccine in the elderly population.

Methods: In a cross-sectional study, we have collected data regarding the onset of symptoms within 72hrs following first dose of COVID-19 Vaccination among elderly people through a direct interview and by phone call, using a questionnaire.

Results: Among 1373 elderly, 445 (32.41%) had no symptoms, while the remaining 928 (67.54%) had developed symptoms. The commonest symptoms were fever 738 (53.75%), pain at local site 536 (39.01%), and body ache 382 (27.82%). All these symptoms were relieved by taking Paracetamol 650mg tablet provided by the vaccination center. The commonest co-morbidities observed were hypertension, diabetes, and ischemic heart disease. There was no mortality.

Conclusion: So far, very few studies have been conducted on the elderly population. Our study has an advantage where it has involved a large number of elderly populations. The majority of the elderly in our study received covishield vaccine. We conclude covishield and covaxin vaccines had minor side effects which were self-limiting and can be considered safe in the elderly population despite having multiple co-morbidities. This study endorses that vaccines are safe in the elderly population irrespective of co-morbidities and increasing age.

Key words: COVID-19 Vaccine, Covaxin, Covishield, Safety, Elderly population

Introduction

COVID-19 infection caused by the SARS COV-2 virus is one of the biggest catastrophes humans have suffered, and it has affected every nation worldwide. In March 2020, the World Health Organization (WHO) declared the Coronavirus disease (COVID-19) outbreak a pandemic. The pandemic has severely affected not only health systems but also economic and social progress globally.

As of December 24, 2021, the world has accounted for 5.4 million[1] deaths so far, with disproportionately high mortality and morbidity among elderly people[2]. It Accounted for 4.73 lakh deaths in India, and Karnataka state accounted for 38,301 deaths so far across all the age groups[3].

COVID-19 infection is caused by a coronavirus called the severe acute respiratory syndrome Coronavirus-2 (SARS-CoV-2). Coronaviruses (CoV) are zoonotic and transmitted between animals and humans. Coronaviruses cause diseases like the Middle East Respiratory Syndrome (MERS),–Severe Acute Respiratory Syndrome (SARS), and more mild illnesses, including the common cold[4].

Cough, fever, difficulty in breathing, shortness of breath, tiredness and fatigue are the most common symptoms of infection with COVID-19[5]. Across the globe, 80% of the infected population experienced mild disease and recovered without requiring hospitalization. Whereas around 20% of people who contracted COVID-19 become more seriously ill and

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have trouble breathing[6]. The infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.

The introduction of different COVID-19 vaccines has brought new hope in the battle against it and has decreased the ongoing crisis. Vaccines contributed significantly to the equitable protection and promotion of human well-being globally. Globally, easy access to a vaccine has particularly protected health care workers and those at risk, like the elderly population and people with co-morbidity. Immunization is the only way to decrease the public health burden and protect against the pandemic's impact on the economy. The vaccine and other control and protective measures are vital at this hour. In the longer term, the vaccine will be used for active immunization of at-risk people to prevent COVID-19. India has taken strong preventive measures to contain the spread of COVID-19 through better diagnostics and treatment. The vaccines provided a solution by enhancing immunity and controlling the disease spread.

On March 1, 2021 the Government of India launched a vaccine for the elderly population against COVID-19. Our college organized an awareness program to promote vaccine usage in the elderly for all the NGOs concerning elderly care across the Vijayapura district. Faculties for the awareness program were nodal officers of the Government of Karnataka, WHO representative of Karnataka state, geriatricians, and physicians.

At present, two COVID-19 vaccines got approval for use in India: the indigenous Covaxin by Bharath biotech; the second is the Covishield manufactured by the serum institute of India.

As of 24/12/2021, India has vaccinated a total of 140,31,63,063[7] people, and in Karnataka, 8,40,79,357[8] received vaccines, and in Vijayapura, 29,15,367 people got vaccinated; out of which 11,46,183[9] were people aged 45 years and above.

As these vaccines got approved for emergency purposes, many trials did not include older people. The elderly usually have impaired immune response, co-morbidities, and immune senescence[10,11]. Hence this study intends to know the safety profile among the elderly population following COVID-19 Vaccination.

Methods:

A total of 1800 elderly got Vaccination in our institute in 2 months. Later the supply of vaccines was stopped by Government agencies. We could collect data from 1373 elderly persons vaccinated after getting Ethical Clearance from the University's committee. It is a cross-sectional study. Statistical analysis was done using IBM SPSS v 20.0.0, and categorical variables were analyzed using proportions and percentages and presented in tables.

Method of data collection: We have collected data regarding the onset of symptoms within 72hrs following Vaccination from older people by two methods using a questionnaire about the immediate post-vaccination experience in the elderly population in Vijayapura, following the first dose of Covishield / Covaxin vaccine. Both verbal and written consent taken before an interview. The two ways were,

1. Direct interview with the elderly whoever visits our geriatric clinic of Shri B M Patil Medical College Hospital and Research Centre, and
2. Telephonic survey was carried out through phone calls registered during Vaccination.

Among 1373, information was collected by direct interview during their visit to the geriatric clinic in 370 (26.95%); in the remaining 1003 (73.05%), data were collected by phone call.

Exclusion criteria: The elderly people excluded were 427 for the following reasons

1. Mobile number provided was not correct
2. Senior citizens were reluctant to answer suspecting spam call or harassment call
3. Few senior citizens deemed not suitable to answer
4. Few citizens did not answer the call
5. Few elderly women phone numbers were of their grand children's, and they could not answer as they were away from them.

Results:

The study results conducted to assess the safety profile in the 1373 elderly population after first dose of the COVID-19 Vaccination are as follows.

Age and Sex Distribution

Most of the recipients were male, 829 (60.38%), whereas females were 544 (39.62%). We categorized age into three groups as 60-74 year, 75-84 year, and ≥85 years, among which they constituted 1100 (80.12%), 237 (17.26%), and 36 (2.62%), respectively. Most of the recipients of the vaccine were in the age group of 60-74 years of age, with male dominance of 60% (Table -1)

Table -1 Age and Sex Distribution

AGE	MALE	%	FEMALE	%	TOTAL	%
60-74 years	642	58.36%	458	41.64%	1100	80.12%
75-84 years	168	70.89%	69	29.11%	237	17.26%
≥ 85 years	19	52.78%	17	47.22%	36	2.62%
Total	829	60.38%	544	39.62%	1373	100.00%

Symptom Analysis

In our study, 445 (32.41%) had no symptoms, while the remaining 928 (67.54%) had developed symptoms post-vaccination within 72 hours. The common symptoms that developed either in single and or combinations of two and more were fever in 738 (53.75%), pain at local site in 536 (39.01%), body ache 382 (27.82%), vomiting 163 (11.86%), loose stools 93 (6.77%), nausea 67 (4.88%), giddiness 24(1.75%), flu-like 22 (1.6%), headache 1 (0.07%), skin rash 1 (0.07%), and cough (0.07%) (Table -2). All these symptoms were relieved by taking Paracetamol 650mg tablet provided by the vaccination centre during Vaccination.

Table -2 Common symptoms developed following COVID-19 vaccination

SYMPTOM	NUMBER	%
Nil	445	32.41%
Fever	738	53.75%
Pain at injection site	536	39.04%
Body ache	382	27.82%
Vomiting	163	11.86%
Loose stools	93	6.87%
Nausea	67	4.88%
Giddiness	24	1.75%
Flu like symptoms	53	3.86%
Headache	1	0.07%
Skin rash	1	0.07%
Cough	1	0.07%

In this study, 53 (3.86%) had suffered from flulike symptoms, among whom 38 (71.7%) were self-isolated and 15 (28.3%) hospitalized, while 2 out of 15 required oxygen support. All have recovered with no mortality.

Co-morbidity

Table -3 Co-morbidity in the participants_

CO-MORBIDITY	NUMBER	%
Nil	188	13.7%
Hypertension	724	52.8%
Diabetes Mellitus	460	33.5%
Ischemic Heart Disease	230	16.8%
Anaemia	140	10.2%
Thyroid Disorder	76	5.6%
Osteoarthritis	70	5.1%
Stroke	41	3%
Chronic Obstructive Pulmonary Disease	34	2.5%
Benign Prostatic Hypertrophy	27	2%

In our study, 188 (13.7%) participants were not having any co-morbidity, while 87% had single or combinations of two or more co-morbidities. The common comorbidities noted were Hypertension 724 (52.8%), Diabetes 460 (33.5%), ischemic heart disease 230 (16.8%), Anaemia 140 (10.2%), Thyroid Disorder 76 (5.6%), Osteoarthritis 70 (5.1%), Stroke 41 (3%), Chronic obstructive pulmonary disease 34 (2.5%), and Benign prostate hypertrophy 27 (2%) (Table -3)

The other co-morbidities noted were obesity, gout, vertigo, depression, bronchial asthma, lumbar spondylosis, hepatitis C, heart failure, post-COVID-19, parkinsonism, schizophrenia, osteoarthritis, pulmonary tuberculosis, carcinoma colon, partial blindness, bronchitis, cancer, hyperlipidaemia, cervical spondylosis, neuropathy, and supraventricular tachycardia in 0.14% each, across the study population.

There was no prior history of COVID-19 infection in the study population.

Table 4: Type of vaccine received

TYPE OF VACCINE	MALE	%	FEMALE	%	TOTAL
COVISHEILD	685	61.16%	435	56.92%	1120 (81.57%)
COVAXIN	144	38.84%	109	43.08%	253 (18.43%)
TOTAL					1373

Among 1120 (81.57%) elderly people who received Covishield vaccine, males constituted 685 (61.16%), and females were 435 (38.84%), while 253 (18.43%) received COVAXIN among which the males were 144 (56.92%), and female were 109 (43.08%). (Table -4)

Discussion:

This study was carried out to evaluate the safety profile of vaccines in 1373 elderly population, a direct interview collected the information in 370 (26.95%) participants and 1003 (73.05%) were through a phone call, is similar to a study by Shrijana et al[12].

In our study, male dominance was noted and is similar to a survey by Jayadevan et al[13], with male (56%) and female (44%), while Shrijana et al[12], had female (64.8%) dominance.

In our study, 1100 (80.12%) were in the young-old (60-74years) age group, whereas in a study conducted by Ramasamy et al[14], in phase 2/3 trial included 160 aged 56-69 and 240 aged above 70 years.

In our study, the majority, 81.57% elderly people, received the Covishield vaccine, whereas, in a study by Jayadevan et al[13], 95% received Covishield, 3.3% received Covaxin, and 0.8% received Pfizer-Biotech and Sinopharm.

Overall, 928 (67.54%) of recipients reported at least one symptom within 72hrs post-vaccination in our study, which is similar to a study by Jayadevan et al[13], of 65.9% had reported at least one symptom.

The six most common symptoms the elderly had in our study were fever in 738 (53.75%), pain at injection site 536 (39.01%), body aches 382 (27.82%), vomiting 163 (11.86%), loose stools 93 (6.77%), and headache in (0.07%). While in the study by Jayadevan et al[13], they reported tiredness (45%), myalgia (44%), fever (34%), headache (28%), and pain at a local site (27%). The study by Shrijana et al[12], reported pain at the injection site (55%), fever (37.1%), myalgia (30.1%), lethargy 1102 (27.6%), and headache in 1051 (26.3%). Ramasamy et al[14], reported fatigue, headache, feverishness, and myalgia were the most solicited systemic adverse reactions. In a study by Voysey M et al[15], the most frequently reported adverse reactions were injection site tenderness (60%); injection site pain, headache, fatigue (50%); myalgia, malaise (40%); pyrexia, chills (30%); and arthralgia, nausea (20%). (TABLE 5)

TABLE 5: Symptoms comparison in various studies following COVID-19 Vaccination

SYMPTOMS	Jayadevan et al	Shrijana et al	Ramasamy et al	Voysey M et al	OUR STUDY
Fever	34%	37.1	-	30%	53.75%
Pain at injection Site	27%	55%	25%	50%	39.01%
Body ache	44%	30.1%	-	40%	27.82%
Vomiting	1%	-	-	20%	11.86%
Loose stools	1%	-	-	-	6.77%
Headache	1%	26%	20%	-	0.07%

Our study reported rash over the skin in one patient following Vaccination, whereas a study by Shukla S C et al[16], reported no case.

In our study, serious adverse events and mortality have not occurred, similar to studies by Jayadevan et al[13], and Ramasamy et al[14], whereas Shrijana et al[12], mentioned three anaphylactic reactions which got treated, and no mortality occurred.

Conclusion:

So far, very few studies on vaccine safety have involved the elderly population. Our study has the advantage of a large number of the elderly people of Vijayapura, Karnataka, engaged in the study for the safety profile after first dose of Vaccination. Fever was the most typical mild symptom noted. The majority received Covishield. We conclude that Covishield and Covaxin had minor self-limiting side effects and can be considered safe among the elderly population. This study promotes safety and removes the hesitancy of vaccine use in the elderly population despite having co-morbidity.

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