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SURVEY ON POST VACCINATION REACTIONS IN INDIANS AFTER COVAXIN AND COVISHIELD VACCINATION

SATYALAKSHMI S^{*1}, RAMYA N², SUSHMA K¹, AKSHAY A¹, GUNA U¹ AND
RAMARAO B¹

- 1: Department of Pharmaceutical Biotechnology, Faculty of Pharmacy, Vignan Institute of Pharmaceutical Technology, Duvvada, Visakhapatnam, Andhrapradesh, India, 530049
2: Department of Mathematics, Vignan's Institute of Information Technology (Autonomous), Duvvada, Visakhapatnam, Andhrapradesh, India, 530049

*Corresponding Author: Dr. S. Satya Lakshmi: E Mail: satyalaxmi148@gmail.com

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ABSTRACT

India has started vaccination against Covid-19 on 16th January 2021. Till now, approximately 88 lakhs people between 18-44 years, 90 lakhs of Indians between 45-60 years, and 67 lakhs of Indians above 60 years were vaccinated with the currently approved vaccines. All vaccines available in India can produce some common adverse reactions. A Survey was conducted by asking a questioner through a phone call to vaccinated individuals. A total of 3127 people above 45 years, who were vaccinated with covaxin and covishield from 02.03.2021 to 29.03.2021 have participated in this survey. Fever, headache, fatigue, myalgia, flu-like symptoms, pain at the site of injection, and joint pains were the common post-vaccination reactions were observed in more than 50% of vaccinated people. Only 4 deaths were happened out of 3127 people. Paired t-test was applied to evaluate the post-vaccine adverse reactions. Null hypothesis (H₀) was accepted (P>0.05), people vaccinated with two brands of vaccines equally suffered from feverish symptoms. Null hypothesis (H₀) was rejected (P<0.05), there is a significant difference in the vaccinated people suffering from body pains. Severe body pains were observed in Covishield

vaccinated people. There is no gender difference observed in this study both the genders equally reported the adverse reactions. This survey can improve the confidence in government-approved vaccines. This study helps to educate the public, dispelling misinformation, and reduce hesitancy on the vaccine.

Keywords: Survey, Covaxin, Covishield, Post-vaccination, adverse reactions, Myalgia

INTRODUCTION

First time in December 2019, a novel coronavirus was reported in china people from Wuhan by screening the patients who suffered from viral pneumonia symptoms [1-3]. Next-generation sequencing was helped to identify the people infected with the coronavirus. It was provisionally called as 2019 novel coronavirus (2019- nCoV), and the infection caused by this virus was officially named COVID-19 [4].

The manifestations of COVID-19 infection were varied from common flu signs to severe fatal conditions covered-fever or chills, coughing, breathlessness, fatigue, muscle ache, headache, nausea or vomiting, sore throat, congestion or running nose, diarrhea, loss of smell (anosmia), and loss of taste (ageusia) [5, 6]. 80% of the people suffering from mild symptoms of Covid-19, severe signs are in 50% of the affected people and 5% are with critical conditions like a failure of multi-organs and respiratory shock.

The present treatments such as plasma therapy, usage of interferons, monoclonal antibodies, and pharmaceuticals are not

eliminating covid 19 infection completely. Immunization is the best way to get rid of this infection. Nearly 200 countries in the world started the covid 19 vaccination program. Some countries vaccinated 80% of their population. Currently, ten numbers of vaccines are available. Some more vaccines are under phase 2 and phase 3 trials. Some vaccines are waiting for regulatory approval. India approved three vaccines to date. The Serum Institute of India was made covishield vaccine in association with British pharmaceutical company AstraZeneca [7-9]. The vaccine is made from a weakened version of a common cold virus (known as an adenovirus) from chimpanzees [10]. The frequently reported adverse reactions in clinical subjects are tenderness at the site of injection, pain at the injection site, fatigue, headache, myalgia, malaise, pyrexia, chills, arthralgia, and nausea [11]. Covaxin, made by Bharat Biotech in collaboration with the Indian Council of Medical Research (ICMR). Covaxin is an inactivated vaccine that is made up of killed coronaviruses.

Pain/swelling/redness/itching at the site of injection, headache, fever, malaise/body ache, nausea, vomiting rashes are the reported covaxin side effects [11] (Covaxin fact sheet). These two vaccines are available in India from Jan 16th, 2021, and supplied 228.5 million doses.

In April 2021, the Indian government approved the Russian Sputnik V vaccine (which is distributed locally by Dr. Reddy's Laboratories) as a third vaccine, which began use in May 2021 [8]. It uses a cold-type virus, engineered to be harmless, as a carrier to deliver a small fragment of the coronavirus to the body [10]. As of 23 June 2021, India has administered 301,626,028 doses overall, including first and second doses of the currently approved vaccines [5, 6]. Covishield 261.3 million, covaxin 35.38 million, and sputnik V 0.05 million vaccines were received by Indians [7, 8]. 131.8 million men, 112.9 million women took the shots of vaccination. India Today reported that many Indians still refusing to take Covid-19 vaccine due to misinformation [9]. With this background, we have surveyed on covishield and covaxin post-vaccination adverse reactions on the Indian population.

METHODS

The mobile phone survey was conducted for better identification of Post covid vaccination

adverse reactions. We have conducted interactive voice response (IVR) surveys with created questionnaires that contain nearly 15 questions. We made sixty to seventy phone calls every day and gathered information by asking the above questionnaires. This survey was done on the populations who have received vaccination from Community health center Aganampudi, Visakhapatnam from 02.03.2021 to 29.03.2021.

Statistical analysis:

Fatigue, fever, body pains, chills, headache, and pain at the site of injection are major adverse reactions identified in a high percentage of vaccinated people. Paired t-test was employed to determine the occurrence of two variables such as pain and fever between covaxin and covishield vaccination.

RESULTS

Among 3127 vaccinated people were responded to our survey and gave relevant answers. Among them, most of the people were belong to Anganampudi (Visakhapatnam District) and its surrounding areas, above 45 years maximum between 60 and 70 years above age group. 1452 members received covishield and 1675 were received covaxin. 56.6% of men and 43.4% of women responded to our survey. The percentage of the people affected by various

post-vaccination was shown in the bar diagram (Figure 1).

The Paired t-test was employed to determine whether there is any significant difference between adverse reactions identified in the male and female population, separately for covaxin and covishield vaccines (Table 1), taking null hypothesis as H0: There is no significant difference in adverse reactions identified in male and female.

Further, the Paired t-test was employed to check is there any significant difference in the percentage of vaccinated people suffering from fever and body pains as two variables, taking covaxin and covishield as two samples. Here null hypothesis is considered as H0: There is no significant difference in people suffering from fever and body pains.

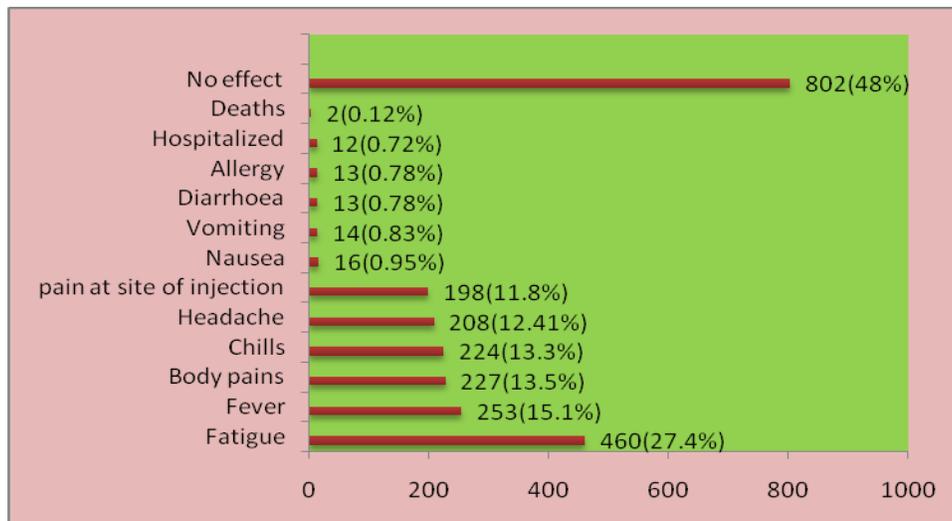


Figure 1: Bar diagram showing the percentage of adverse reactions observed covaxin vaccinated people

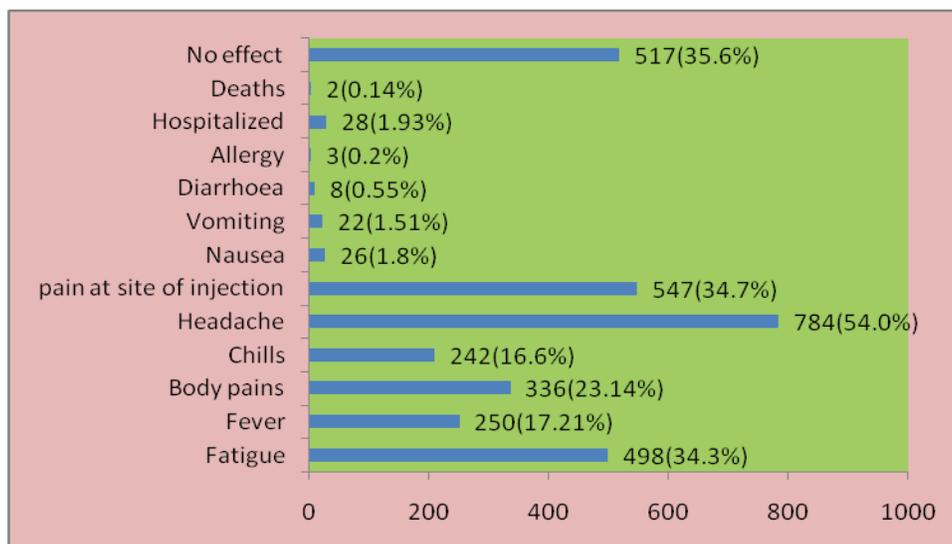


Figure 2: Bar diagram showing the percentage of adverse reactions observed covishield vaccinated people

Table 1: Paired t-test taking two genders as variables (covishield)

	Variable 1	Variable 2
Mean	63.38462	48.30769
Variance	423.5897	349.8974
Observations	13	13
Hypothesized Mean Difference	0	
df	24	
t Stat	1.695316	
P(T<=t) one-tail	0.051476	
t Critical one-tail	1.710882	
P(T<=t) two-tail	0.102953	
t Critical two-tail	2.063899	

Table 2: Paired t-test taking two genders as variables (covaxin)

	Variable 1	Variable 2
Mean	63.06667	48.6
Variance	812.781	349.5429
Observations	15	15
Pooled Variance	581.1619	
Hypothesized Mean Difference	0	
df	28	
t Stat	0.053014	
P(T<=t) one-tail	0.479049	
t Critical one-tail	1.701131	
P(T<=t) two-tail	0.958097	
t Critical two-tail	2.048407	

Table 3: Paired t-test taking two samples (covaxin and covishield) for severity of fever

	23	8
Mean	18.91667	18.5
Variance	70.62879	71.72727273
Observations	12	12
Pearson Correlation	0.276524	
Hypothesized Mean Difference	0	
df	11	
t Stat	0.142225	
P(T<=t) one-tail	0.444737	
t Critical one-tail	1.795885	
P(T<=t) two-tail	0.889474	
t Critical two-tail	2.200985	

Table 4: Paired t-test taking two samples (covaxin and covishield) for determination of body pains

	29	24
Mean	25.58333	15.66666667
Variance	119.9015	46.06060606
Observations	12	12
Pearson Correlation	0.286658	
Hypothesized Mean Difference	0	
df	11	
t Stat	3.092973	
P(T<=t) one-tail	0.005116	
t Critical one-tail	1.795885	
P(T<=t) two-tail	0.010232	
t Critical two-tail	2.200985	

DISCUSSION

Among the vaccinated individuals, 50% were above 60 and 60 years of age. Most of the people vaccinated with covaxin suffered from fatigue followed by fever, body pains, chills, headache, and pain at the site of injection shown in **Figure 1**. The percentage of vaccinated people who suffered from adverse reactions with covaxin was less compared to covishield. With covishield more than 50% of the people suffered from headache, followed by pain at the site of injection, fatigue, body pains, fever, and chills (**Figure 2**). In a very less percentage of people, the following adverse reactions were identified with both brands-nausea, vomiting, diarrhea, and allergic symptoms. A very little number of people were hospitalized. A total of four vaccinated people were died because of their previous health history.

By applying the t-test we observed from **Table 1 & 2** the P-value is greater than 0.05 ($P > 0.05$) confirms that there is statistically no significant difference between the two genders suffering from post-vaccination symptoms received covishield and cavaxin. From **Table 3** it is observed that the P-value is more than 0.05 ($P > 0.05$) indicating that there is no significant difference in covaxin vaccinated and covishield vaccinated people suffering from fever. This means that both

the vaccinated people suffered from fever equally. From **Table 4** it is observed that the P-value is less than 0.05 ($P < 0.05$) indicating that there is a significant difference between the covaxin and covishield vaccinated people suffering from body pains. More number of the covishield vaccinated people suffered from body pains compared to covaxin received people. Tiredness, myalgia, and fever were observed in 5396 people who were vaccinated in one week from 29 January to 4 February [20].

CONCLUSION

More than 50% of the people above 45 years of age who were vaccinated in March participated in the survey, reported mild and short-lived post-vaccination symptoms. Tiredness, body pains, and fever were most commonly reported. Among 3127 vaccinated people, most of them were above 60 years of age group, this may be the reason approximately 50% of individuals not reported any post-vaccination symptoms. There was a slight difference in symptoms among those who had taken covishield and covaxin.

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The entire authors have contributed equally.

CONFLICT OF INTEREST STATEMENT

The authors declared no conflict of interest in the manuscript.

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