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A Study on Health Related Quality Of Life of Post Immunized Subjects of Covid-19 in Tertiary Care Hospital

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ABSTRACT: World Health Organization (WHO) declared Corona Virus 2 (SARS CoV2), a pandemic that causes a type of acute respiratory syndrome causing widespread mortality and sickness but it also decimated the economies of the countries. In order to prevent the infection from spreading, vaccinations were developed so that pre sensitization of the virus provides acquired immunity. The process of developing immunity following vaccination can induce adverse reactions which might lead to decrease in the quality of life of subjects. Thus it's important to assess the quality of life of subjects who received the vaccine. The study was conducted in 1802 subjects with equal distribution in population receiving covaxin or covishield for a period of 6 months in Trauma Care center and Krishna Rajendra Hospital attached to Mysore Medical College and Research Institute (MMCRI). The quality of life of subjects receiving either of covaxin or covishield were assessed using BREF's scale. The quality of life was assessed by calculating the 4 domains of the scale separately. There were differences observed between the quality of life of subjects receiving either of the vaccination with overall increased quality of life for subjects receiving covaxin rather than covishield. But the differences observed were negligible.

KEYWORDS:BREF's scale, vaccine, quality of life, covaxin, covishield

I. INTRODUCTION

SARS (Severe Acute Respiratory Syndrome) is a type of acute respiratory syndrome. The World Health Organization declared Corona Virus 2 (SARS CoV2), a corona virus that causes COVID 19 infection, a pandemic on March 11, 2020. The epidemic not only caused widespread mortality and sickness but it also decimated the economies of the countries[1].

When germs infiltrate our bodies, such as the COVID-19 virus, they infect and develop causing illness, known as an infection. In order to combat infection, our immune system have a number of mechanisms like innate immunity and acquired immunity in which pre sensitization of the virus provides acquired immunity activating the B lymphocytes and memory T lymphocytes and in turn boosting the immune system[2,3].

It may take many days or weeks for a person's body to develop and activate all of the germ-fighting systems necessary to recover after being exposed to the virus that causes COVID-19.The person's immune system recalls what it learnt about how to defend the body against the illness after the infection. A small number of T-lymphocytes known as "memory cells" are kept in the body and activate fast if the body comes into contact with the same virus again. B-lymphocytes generate antibodies in response to the detection of known antigens. Experts are currently figuring out how long these memory cells can protect a person against the COVID-19 virus. For the purpose of generating these memory cells, different types of COVID vaccines were discovered[3].

Different vaccinations provide protection in different ways. All vaccines, on the other hand, leave the body with a supply of "memory" T- and B-lymphocytes that recognize how to resist the virus in the future. The body generally produces T-lymphocytes and B-lymphocytes a few weeks following immunization. As a result, a person might become infected with the virus that causes COVID-19 soon before or shortly after immunization and become ill as a result of the vaccine failing to offer adequate protection. The process of developing immunity following vaccination can sometimes induce symptoms such as fever. These symptoms

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are healthy and indicate that the body is strengthening its defenses.

Mild side effects appear to be tolerable after COVID-19 immunization since the body will require time to adjust to the vaccine dosage and activate the immune system to produce protective antibodies. As a result, the general public should be aware of these minor side effects, which can be managed with symptomatic treatment such as paracetamol to resolve symptoms quickly, or such medicine should be taken as prophylaxis to avoid developing post-vaccination symptoms and increase acceptance of the COVID-19 vaccine among the general population while reducing the psychological fear of any SARS-CoV-2 vaccination side effects, which would undoubtedly help to combat it[4].

And also educating public on quality of life of people of those already taken either of the vaccine makes it more appealing for others to believe that it is safe to get vaccinated. Thus the study "A Study on Health Related Quality of Life of Post Immunized Subjects of Covid-19 in Tertiary Care Hospital" was carried out to bring out insight for general public on how the quality of life of people will be affected so that they all are motivated to get vaccinated as soon as possible.

II. MATERIALS & METHOD

Materials

- Data collection form
- Patient interview
- BREF's scale
- Other relevant sources

Method and collection of data

Study site: The study was conducted on the Trauma Care center and Krishna Rajendra Hospital attached to Mysore Medical College and Research Institute (MMCRI). The study site was selected based on the vaccination drive arranged by District Administration of Mysuru along with Ministry of Health and Family Welfare, Government of India.

Study design: This was a prospective observational study.

Study period: The study was carried out for a period of 6 months.

Study criteria: The study was carried out by considering the following inclusion and exclusion criteria after taking consent form from the patients in a suitably designed informed consent forms.

Inclusion criteria

1. Subjects receiving either of the two COVID-19 vaccines (Covishield/Covaxin).
2. Subjects of >45 years.
3. Subjects of both genders.
4. Subjects that had taken both the doses.

Exclusion criteria

1. Pediatric, pregnant and adult subjects.
2. Patients who are non-co-operative.
3. Patients who are not willing to be immunized

Study protocol and Informed consent

Each subject soon after vaccination was approached and the purpose of the study was explained. The consent of the subject was taken for their inclusion in the study and subjects cooperation and participation was overwhelming.

Study procedure

1. Recreation of data-collection form:
   - A specially designed data-collection form was devised for the study. All data of the enrolled subjects involving demographic details, type of vaccination, date of last dose of vaccine received, contact details were collected from various data sources.
   - The same details were electronically documented in specially designed database.
2. Patient enrolment:
   - All subjects meeting the study-criteria were enrolled in the study after obtaining the informed consent.
   - All the 1802 subjects enrolled in the study were followed-up aftervaccination was completed.
3. Data collection:
   - All relevant details of the enrolled subjects were obtained from telephonic interview and were documented in the data-collection form.
4. Assessment of quality of life using BREF's scale:
   - The assessment of subject's quality of life was done based on WHO BREF'S quality scale.
   - Results were analyzed based on the study objectives with suitable method.

Statistical Method

Statistical analysis were carried out using ANOVA to determine the means of two immunization groups by using IBM SPSS Software.

Ethical approval

Ethical clearance for this study was obtained from the Institutional Ethics Committee, Mysore Medical College and Research Institute and Associated Hospitals, Mysore with IECREF no – Clinical pharma/CR-366/2021.

III. RESULT

The quality of life of subjects receiving either of covaxin or covishield was assessed using BREF's

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scale. The quality was assessed by calculating the 4 domains of the scale separately.

AGE GROUP DISTRIBUTION

The basic demographic details were analyzed and were tabulated. Figure 1 explains the age group distribution of vaccinated subjects. Subjects belonging to age group 45-55 were found to be 35.1% among subjects receiving covishield and were more prominently observed. Among the subjects vaccinated with covaxin, 38% of them belonged to age group 55-65 age.

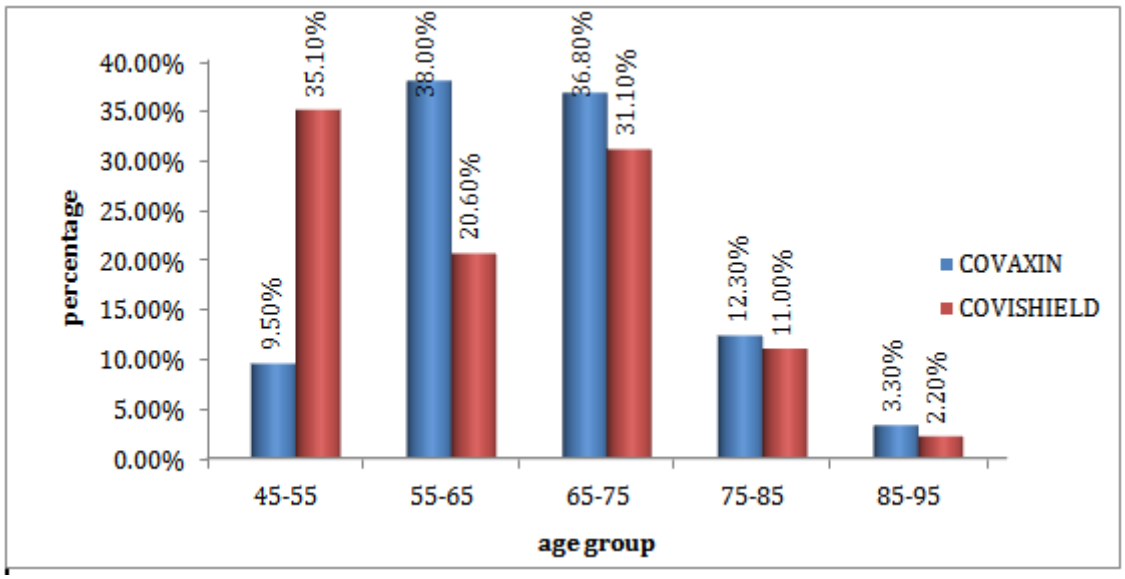

Figure 1: AGE GROUP DISTRIBUTION

GENDER DISTRIBUTION

In figure 2, gender distribution explains that male dominated in the study population over both types of vaccinations. In covaxin population it was 58.16% of males and in covishield it was 52.28% of males.

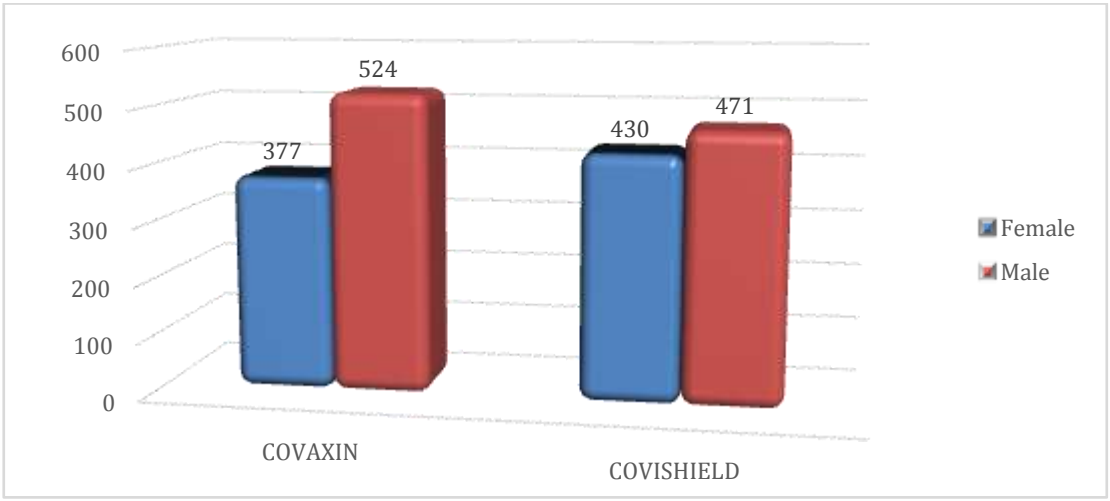

Figure 2: GENDER DISTRIBUTION

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PARAMETERIC DISTRIBUTION

The mean and standard deviation of the parameters that were to be analyzed were tabulated separately for both covaxin and covishield. The mean and standard deviation of age group in both covaxin and covishield were 66.19± 9.35 and62.46± 11.14. The Q1 refers to the overall quality of life of subjects which was justified by every subject. This suggested that quality of life of subjects that received covaxin had mean quality of life of 4.9±0.37 out of 5 whereas covishield received subjects had 4.64±0.48.

Table 1: PARAMETERIC DISTRIBUTION

	COVAXIN		COVISHIELD	
	Mean	**St. Deviation**	**Mean**	**St. Deviation**
Age group	66.19	9.35	62.46	11.14
Q1	4.9	0.37	4.64	0.48
Q2	4.9	0.37	4.77	0.43
Physical health (D1)	34.28	2.09	32.68	3.08
Psychological (D2)	29.55	1.6	30	0
Social relationships (D3)	14.91	0.28	14.65	0.55
Environmental (D4)	39.03	2.59	39.47	1.1
Total QOL	117.78	6.22	116.8	5.35

The Q1 (How do you rate your quality of life) and Q2 (How satisfied are you with your health) questionnaires of BREF's scale evaluated the overall quality of life and health as explained by the subjects and in both cases subjects receiving covaxin had greater quality of life than subjects receiving covishield. Also here covaxin had greater quality of life in regards to physical health and social relationships while compared with covishield. While covishield had greater quality of life with regards to the psychological and environmental domains. In overall the quality of life of subjects receiving covaxin was more than the quality of life of subjects receiving covishield.

The analytical statistics ANOVA technique were used and the significance was found to be <0.001 with F value of 15.371. This suggests that there was a significant difference between the quality of life in subjects receiving individual vaccines but those differences were negligible.

AGE GROUP * QOL CORRELATION

In table 2 the age group distribution of subjects along with their quality of life with their respective received vaccination. The quality of life of subjects belonging to each age group was observed with not much of a difference or no difference within each of vaccination group.

Table 2: AGE GROUP * QOL CORRELATION

AGE GROUP	COVAXIN		COVISHIELD	
	Mean	**Frequency**	**Mean**	**Frequency**
45-55	117.77	86	116.93	316
55-65	117.78	342	116.8	186
65-75	117.78	332	116.78	280
75-85	117.76	111	116.81	99
85-95	117.72	30	116.97	20

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The level of significance of the group with relation to quality of life was found to be 0.001 which is way less than 0.05 and the F value was found to be 4.83. This suggests that even though the quality of life of subjects within the different age group is not having much difference but the observed difference is significant and the quality decreases on increasing of age in covaxin subjects while in covishield subjects the quality decreased at first and then increased to the maximum of quality of life in 85-95 age group

GENDER * QOL CORRELATION

In table 3 depicted below explains that there were no difference between the quality of life of subjects based on their gender distribution. The analytical statistics for the gender distribution and their quality of life were evaluated and found the significance to be 0.603 which explains that the difference is statistically insignificant with F value of 0.506.

Table 3: GENDER * QOL CORRELATION

GENDER	COVAXIN		COVISHIELD	
	Mean	Frequency	Mean	Frequency
FEMALE	117.78	377	116.81	430
MALE	117.78	524	116.8	471

IV. CONCLUSION

It's not certain that quality of life of subjects receiving the vaccines get affected. It depends on the type of vaccine one receives and also the age group of the subjects. Even though the quality of life of subjects receiving either of vaccines had no much difference, the slightest of the differences were found to be significant. Considering physical and social relationship domain, subjects receiving covaxin had increased quality of life than covishield receiving subjects. While covishield receiving subjects had comparatively high quality of life than covaxin in the domain of psychological and environmental. So in our study, in overall subjects receiving covaxin had slightly increased quality of life than covishield received subjects.

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