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Research Paper

A Study to Assess the Adverse Ocular Events Following Covid-19 Vaccination Among Vaccinated Adults In A Selected Community Area, Puducherry.

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ABSTRACT:
A COVID‐19 vaccination is intended to provide acquired immunity against severe acute respiratory syndrome coronavirus 2 (SARS - CoV-2), the virus that causes coronavirus disease 2019 (COVID‐19). Common side effects of COVID‐19 vaccination include soreness, redness, rash, inflammation at the injection site fatigue, headache, myalgia (muscle pain), and arthralgia (joint pain), which resolve without medical treatment within a few days. The main objectives of the study is to assess the effectiveness of ocular events following COVID-19 vaccination among the vaccinated adults in a selected community area, Puducherry. The research approach used for this study is quantitative research approach. A descriptive research design was adopted for the present study. The descriptive research design was adopted for this study. By using convenient sampling technique, 50samples of COVID-19 vaccinated adults in the community area was selected for the present study. The study was conducted in the community area at thirubuvanai , Puducherry who meets the inclusion criteria. This study had preliminary effort that focused on assessing the ocular events following COVID- 19 vaccinated adults . On the basis of the study results majority of the vaccinated adults 29(58%) had Moderately affected, 15(30%) had Mildly affected and 6(12%) had Severely affected and the mean and standard deviation the level of adverse ocular events following covid19 vaccination among vaccinated adults is (29.58+8.45) respectively.

Keywords: *Adverse ocular events, COVID-19 vaccination, Vaccinated Adults*

I. INTRODUCTION:

A COVID‐19 vaccination is intended to provide acquired immunity against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease 2019 (COVID‐19).

Common side effects of COVID‐19 vaccination include soreness, redness, rash, inflammation at the injection site, fatigue, headache, myalgia (muscle pain), and arthralgia (joint pain), which resolve without medical treatment within a few days.

Several ophthalmic manifestations of the COVID-19 vaccinations have been reported by ophthalmologists. Posterior segment, including the uvea, choroid and retinal vasculature, was most commonly affected and the clinical features developed at a median of four days from the time of vaccination. The possible mechanisms include molecular mimicry of the COVID-19 vaccination components with host ocular tissues, antigen-specific cell and antibody-mediated hypersensitivity reactions to viral antigens and adjuvants present in the vaccines. The causal relationship of the ocular signs and symptoms and COVID-19 vaccination has not been established and requires long-term and large multicentre data. Most of the manifestations are mild, transient and adequately treated when diagnosed and managed early. The benefits of COVID-19 vaccination outweighs the rare adverse events and should not be a deterrent to vaccination.

The COVID-19 vaccinations have been found to be 94%–95% effective. The eyelid, ocular surface, and cornea are easily observable by patients and, therefore, present as soon as the symptoms develop. These usually start within 24—48 hours of the inoculation and last for 1–2 days.

As 9 November 2023, 13.53 billion doses of COVID‐19 vaccines have been administered worldwide, based on official reports from national public health agencies. By December 2020, more than 10 billion vaccine doses had been preordered by countries, with about half of the doses purchased by high-income countries

comprising 14% of the world's population. Despite the extremely rapid development of effective mRNA and viral vector vaccines, worldwide vaccine equity has not been achieved. The development and use of whole inactivated virus (WIV) and protein-based vaccines have also been recommended, especially for use in developing countries. The 2023 Nobel Prize in Physiology or Medicine was awarded to Katalin Karikó and Drew Weissman for the development of effective mRNA vaccines against COVID-19.

All vaccines that are administered via intramuscular injection, including COVID‑19 vaccines, have side effects related to the mild trauma associated with the procedure and the introduction of a foreign substance into the body. These include soreness, redness, rash, and inflammation at the injection site. Other common side effects include fatigue, headache, myalgia (muscle pain), and arthralgia (joint pain), all of which generally resolve without medical treatment within a few days. Like any other vaccine, some people are allergic to one or more ingredients in COVID‑19 vaccines. Typical side effects are stronger and more common in younger people and in subsequent doses, and up to 20% of people report a disruptive level of side effects after the second dose of an mRNA vaccine. These side effects are less common or weaker in inactivated vaccines.COVID‑19 vaccination-related enlargement of lymph nodes happens in 11.6% of those who received one dose of the vaccine and in 16% of those who received two doses.

NEED FOR THE STUDY

International level

A stepwise approach for developing any new vaccine involves vaccine development, clinical trials, U.S. Food and Drug Administration (FDA) approval or authorization, manufacturing, and distribution. The COVID-19 vaccines were developed at an unprecedented pace and were given Emergency Use Authorizations (EUAs). As of 19 September 2022, a total of 12,640,866,343 vaccine doses have been administered. COVID-19 vaccines and updated/bivalent COVID-19 boosters are effective at protecting people from being hospitalized, serious illness, and death.

The Vaccine Adverse Event Reporting System (VAERS) was developed by the U.S. Food and Drug Administration (FDA) in 1990 as a national early monitoring system for vaccine safety. The commonly reported adverse effects of COVID-19 vaccinations consist of the injection site's local reaction followed by several non-specific flu-like symptoms. However, several systemic and organ-specific (e.g., eye, heart) adverse effects have also been reported from across the globe. Therefore, it is imperative for ophthalmic health care providers to be familiar with the clinical presentations, pathophysiology, diagnostic criteria, and management of ocular adverse effects following COVID-19 vaccination. Early diagnosis and quick initiation of the treatment may help to provide patients with a more favourable outcome and rule out masquerading entities. With an increasing amount of literature in the form of isolated case-study reports, case series, and analysis of the VAERS database, an epidemiological montage has started to emerge.

National level

A new variant of Covid emerged in Wuhan, China in December 2019 that caused severe respiratory illness. The World Health Organization named this virus SARS-CoV-2 and the pandemic COVID-19. According to Li.Y.D, to address the global morbidity and mortality caused by COVID-19, the development process of COVID-19 vaccines was expedited by undertaking clinical trials in parallel rather than in a linear fashion. Multiple COVID-19 vaccines directly entered clinical trials on humans without preclinical testing in animal models. The COVID-19 vaccination drive has been carried out worldwide and the evidence is overwhelming that irrespective of the type of vaccine taken, the vaccines offered safety and protection against becoming seriously ill or dying due to the different variants of CoV-2.

Steinemann,T.L. and Wertheim, M.S. proposed mechanisms for acute corneal allograft rejection include the reduction in the corneal immune privilege due to systemic immune dysregulation and activation of toll-like receptors on the ocular surface and CD4+ T helper-1 cell immunity. Corneal edema was the leading clinical manifestation, followed by keratic precipitates in patients with corneal graft rejection. Most of the ocular adverse effects reported in the literature had a good to fair prognosis with appropriate management. Therefore, corneal graft recipients should not be discouraged from receiving COVID-19 vaccines or boosters. Additionally, the evidence is insufficient to suggest delaying keratoplasties or uptitrating topical steroid administration after a routine keratoplasty, following primary COVID vaccine or booster administration. In high-risk cases, increasing immunosuppressants in the peri-vaccination period may decrease the risk of immune reactions.

State level

Ilaria Testi et al. [2022] conducted a study on Ocular inflammatory events following COVID-19 vaccination.The result is The MHRA received 300 UK spontaneous suspected reports of ocular inflammatory events following COVID-19 vaccination, with a calculated prevalence of 6.6 events per 1 000 000 vaccinated

individuals. Anterior uveitis was the most common phenotype (58.3%), followed by optic neuritis in 39.3%. Median number of days between vaccination and onset was 8 days. Resolution of the event was seen in 52.3%.

Ocular adverse events following COVID-19 vaccination are of special interest and reporting to local public health allows the Public Health Agency of Canada (PHAC) and Health Canada to continually monitor and assess COVID-19 vaccine safety.

While Health Canada and the PHAC have received a small number of reports of ocular adverse events following COVID-19 vaccination in Canada, the small number does not suggest there are safety concerns with these vaccines. However, we are aware that some members of the ophthalmological community have identified a series of ocular events that have occurred following COVID-19 vaccination that they suspect may be associated with vaccination. In particular, internationally, it is suspected that corneal transplant rejection may be occurring at a higher than expected frequency after COVID-19 vaccination.

STATEMENT OF THE PROBLEM

" A study to assess the adverse ocular events following COVID-19 vaccination among vaccinated adults in a selected community area, Puducherry."

OBJECTIVES OF THE STUDY

- To assess the effectiveness of ocular events following COVID-19 vaccination among the vaccinated adults in a selected community area, Puducherry.
- To associate between the level of adverse ocular events following covid19 vaccination **among vaccinated adults with selected demographic variables.**

II. REVIEW OF LITERATURE

Joo Kyung Park, et al. [2023] conducted COVID-19 vaccine efficacy in the immune compromised population, and possible implications to future vaccination in kidney transplant patients. Since the emergence of the virulent coronavirus in 2019, efforts to tackle the coronavirus-disease-2019 (COVID-19) pandemic have been made globally. The development of the coronavirus disease (COVID) vaccine was a significant breakthrough in ways to tackle the virus. Various research studies have been conducted to identify how the virus works and ways to manage COVID, including the efficacy of the vaccines. However, there is limited data on how these measures work for the immunocompromised, despite the grave impact of these virulent strains in this population. Specifically, this review aims to focus on kidney transplant recipients (KTRs). Studies have suggested that there is significantly lower vaccine response in some immunocompromised groups despite additional booster doses, and hence warrants an augmented or alternative protection against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) for these patients. This suggests a need for alternative or more tailored approach in providing adequate protection against the COVID-19 in these cohorts. Some suggested ways include withholding immunosuppressants before and/or after vaccination, increasing the vaccine doses or reducing intervals and providing a mixture of monoclonal antibody (mAb) or antiviral therapy. However, the appropriate degree of alteration and augmentation, as well as its safety and effectiveness remains to be determined. Furthermore, continuous emergence of more virulent strains, such as the Omicron and its sub-lineages or the Deltacron, emphasises the need for ongoing research to assess the effectiveness of the current treatment against these new variants. Overall, active interest and appropriate updates to COVID-19 guidelines is necessary.

III. RESEARCH METHODOLOGY

RESEARCH APPROACH

A Quantitative research approach was adopted for this study.

RESEARCH DESIGN

The descriptive research design was adopted for this study.

POPULATION

The target population for this study comprises of vaccinated adults at a community area, Puducherry.

SAMPLE

The study sample consists of vaccinated adults in a community area who fulfils the inclusion criteria.

SAMPLE SIZE

Sample size consists of 50 vaccinated adults in a community area.

SAMPLING TECHNIQUE

Convenient sampling technique was used for the present study.

SETTING OF THE STUDY

The study was conducted in a community area, Puducherry.

SAMPLE SELECTION CRITERIA

Inclusion criteria

- COVID-19 vaccinated adults in a community area
- Who are available during the time of data collection

Exclusion criteria

- Who are not available during the time of data collection
- Who are not willing to participate

MAJOR FINDINGS

The study shows that out of the 50 vaccinated adults who were interviewed, Majority of vaccinated adults 17(34%) were in the age group 20-30 years, 25(50%) half of the vaccinated adults were Female and 25(50%) half of the vaccinated adults were were male, 31(62%) were Hindu, 20(40%) were Graduate, Family income 19(38%) were 10,000-20,000, 37(74%) were Married, Number of children 15(30%) were Two, COVID-19 vaccination history 30(60%) were 2nd dose, 36(72%) were had Allergic history to vaccination and 34(68%) were had not any past eye history.

Majority of the vaccinated adults 29(58%) had Moderately affected, 15(30%) had Mildly affected and 6(12%) had Severely affected and the mean and standard deviation the level of adverse ocular events following covid19 vaccination among vaccinated adults is (29.58$\pm$8.45) respectively.

IV. RESULT AND DISCUSSION

The study was conducted to assess the adverse ocular events following COVID – 19 vaccinations among the vaccinated adults in a selected community area, Puducherry. The table 1 shows frequency and percentage wise distribution of the level of adverse ocular events following covid19 vaccination among vaccinated adults. The vaccinated adults 15(30%) had Mildly affected, 29(58%) had Moderately affected and 6(12%) had Severely affected and the mean and standard deviation the level of adverse ocular events following covid19 vaccination among vaccinated adults is (29.58$\pm$8.45) respectively.

The table 2 depicts that the demographic variable, ***Allergic history to vaccination*** had shown statistically significant association between the level of adverse ocular events following covid19 vaccination among vaccinated adults with selected demographic variables.

The other demographic variable had not shown statistically significant association between the level of adverse ocular events following covid19 vaccination among vaccinated adults with selected demographic variables respectively.

Table 1 Frequency and percentage wise distribution of the level of adverse ocular event following covid19 vaccination among vaccinated adults.

(n = 50)

Level of adverse ocular events following covid19 vaccination	FREQUENCY (n)	PERCENTAGE (%)
Mildly affected	15	30
Moderately affected	29	58
Severely affected	6	12
Mean$\pm$Standard deviation	29.58$\pm$8.45	

Figure 1:Percentage wise distribution of level of adverse ocular events following covid19 vaccination among vaccinated adults

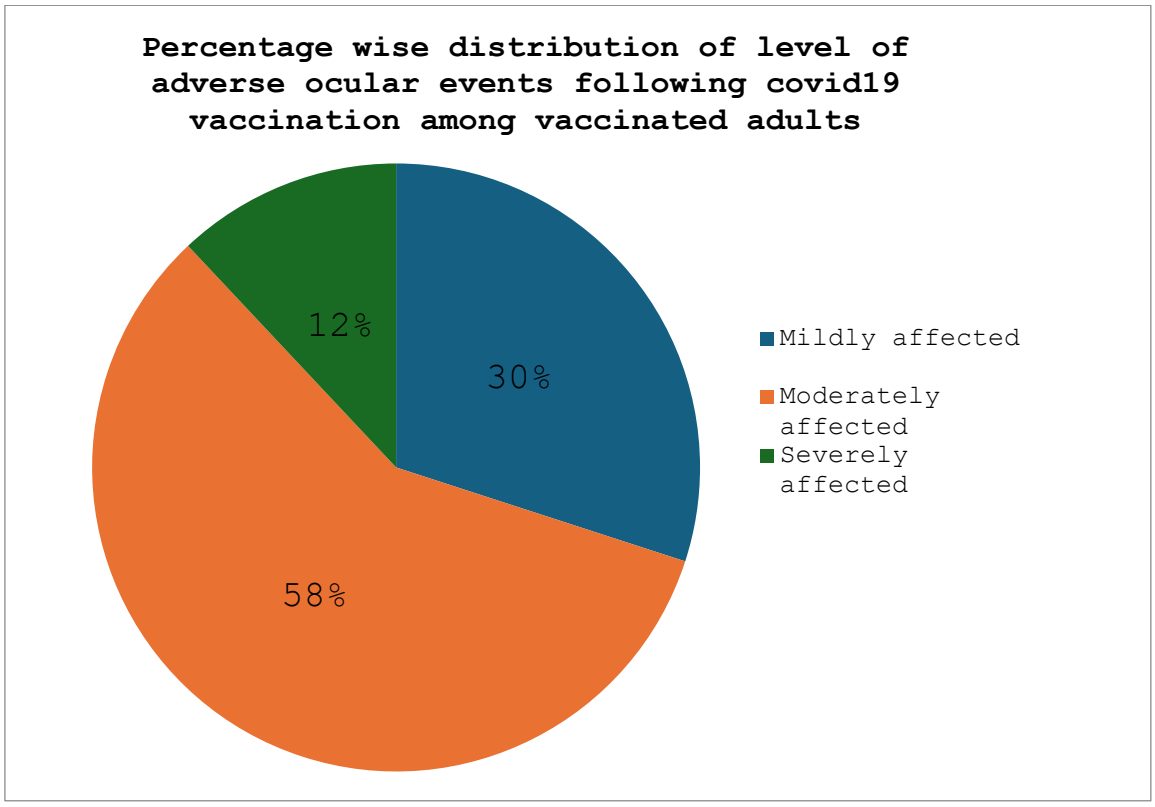

Table 2: Association between the level of adverse ocular events following covid19 vaccination among vaccinated adults with selected demographic variables.

(n=50)

SL. NO	DEMOGRAPHIC VARIABLES	Level of adverse ocular events following covid19 vaccination						Chi-square X^2 and P-Value
		Mildly affected		Moderately affected		Severely affected		
		N	%	N	%	N	%	
1	**Age of the person**							X^2=11.7 Df=6 p =0.068 NS
	20-30 years	5	33.4	10	34.5	2	33.3	
	30-40 years	2	13.3	11	37.9	0	0	
	40-50 years	2	13.3	6	20.7	1	16.7	
	50-60 years	6	40	2	6.9	3	50	
2	**Gender**							X^2=0.76 Df=2 p =0.68 NS
	Male	7	46.7	14	48.3	4	66.7	
	Female	8	53.3	15	51.7	2	33.3	
	Transgender	0	0	0	0	0	0	
	Others	0	0	0	0	0	0	
3	**Religion**							X^2=2.4 Df=4 p =0.65 NS
	Hindu	10	66.7	16	55.2	5	83.3	
	Muslim	3	20	7	24.1	0	0	
	Christian	2	13.3	6	20.7	1	16.7	
	Others	0	0	0	0	0	0	
4	**Educational status**							X^2=1.6 Df=6 p =0.95
	10^{th}	6	40	11	37.9	2	33.3	

	12th	1	6.7	4	13.8	0	0	NS
	Graduate	6	40	11	37.9	3	50	
	Illiterate	2	13.3	3	10.3	1	16.7	
5	**Family income**							X^2=3.3 Df=6 p =0.76 NS
	5000-10,000	5	33.3	9	31	2	33.3	
	10,000-20,000	6	40	11	37.9	2	33.3	
	20,000-30,000	0	0	1	3.4	1	16.7	
	Others	4	26.7	8	27.6	1	16.7	
6	**Marital history**							X^2=1.01 Df=2 p =0.6 NS
	Married	10	66.7	23	79.3	4	66.7	
	Unmarried	5	33.3	6	20.7	2	33.3	
	Divorced	0	0	0	0	0	0	
	Others	0	0	0	0	0	0	
7	**Number of children**							X^2=8.4 Df=6 p =0.20 NS
	One	2	13.3	10	34.5	1	16.7	
	Two	3	20	11	37.9	1	16.7	
	More than two	4	26.7	2	6.9	2	33.3	
	No	6	40	6	20.7	2	33.3	
8	**COVID-19 vaccination history**							X^2=7.9 Df=4 p =0.09 NS
	1st dose	1	6.7	8	27.6	3	50	
	2nd dose	11	73.3	18	62.1	1	16.7	
	Booster dose	3	20	3	10.3	2	33.3	
	Not taken	0	0	0	0	0	0	
9	**Allergic history to vaccination**							**X^2=45.3 Df=2 p =0.000 **HS**
	Yes	1	6.7	29	100	6	100	
	No	14	93.3	0	0	0	0	
10	**Any past eye history**							X^2=3.7 Df=2 p =0.15 NS
	Yes	4	26.7	8	27.6	4	66.7	
	No	11	73.3	21	72.4	2	33.3	

V. CONCLUSION

This study had preliminary effort that focused on assessing the ocular events following COVID- 19 vaccinated adults . On the basis of the study results majority of the vaccinated adults 29(58%) had Moderately affected, 15(30%) had Mildly affected and 6(12%) had Severely affected and the mean and standard deviation the level of adverse ocular events following covid19 vaccination among vaccinated adults is (29.58+8.45) respectively.

VI. RECOMMENDATIONS

- The study can be done in various work settings.
- The study can be done in a large population.

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