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COVID-19 vaccination and abnormalities in indian population

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ABSTRACT: COVID-19 vaccination has been reported to have had some side effects or abnormalities. These abnormalities have been reported after 1 - 2 years after the first dosage. In this paper, we want to investigate if this is true in Indian Population using the Indian Health Authority (IHA) data from January 2022 to December 2022. From this database, we selected a sample data which is a portion of the people living in the great of city of New Delhi. All the sample data contained adults who are > 18 years of age and were either vaccinated or unvaccinated (Sample size n = 11,341,189). In the abnormalities, we particularly want to study if there are any changes to iron deficiency in women particularly as Indian women suffer from low Iron naturally. From the results we found out that the abnormalities after a 3-month period after the vaccination were higher than those in nonvaccinated patients. COVID-19 mRNA vaccine was associated with this new development of nutritional anaemia and aplastic anaemia which were detected in the sample study. The risk of other abnormalities like coagulation defects were also increased after the vaccination and there was also no other risks mRNA vaccine and other viral vector vaccine. We conclude that COVID-19 vaccination did increase the risk of anaemia furthermore than it was before. We find that, education, accessibility of more nutritional food and vitamin intake is the solution for the people suffering from anaemia due to vaccine administration.

KEYWORDS: COVID-19, vaccine, abnormality, anaemia, coagulation.

1 INTRODUCTION

When the COVID-19 hit the world, the immediate and the only step that could have been done was administer COVID-19 pandemic. Governments around the world went on over drive to effectively control the vaccination for large population. To facilitate this response to their own respective population, governments especially in the west, came up with a rapid response developing two types of COVID-19 vaccines, one was Messenger RNA (mRNA) based, which included Pfizer and Moderna in USA and viral vector-based vaccines which were developed by Johnson and Johnson in USA and AstraZeneca in UK [1]. By the end of December 2023, all viral vector, mRNA, and protein-based subunit vaccines had been approved for use by the World Health Organization (WHO) [2]. These vaccines were very effective in stopping and controlling. and preventing infections, deaths, complications which would have led to more hospitalization, death and long COVID-19 cycle [3-5]. There were lot of side effects of COVID-19 vaccination [6-7] which included immune-mediated diseases [8-12]. Vaccine-induced thrombosis with thrombocytopenia (VITT) was a well know complication which was also a serious complication of COVID-19 vaccination [13], [27]. Most cases of VITT caused by COVID-19 utilized a recombinant adenoviral vector encoding the spike protein antigen [14-15]. There were cases where VITT was reported after Pfizer and Moderna vaccine [16], [27], [28], [29].

The autoimmune hemolytic anemia [12, 17] along with Aplastic anemia which is an immune reaction [18], [30], [31], [32], [33], [34] was reported to be one of the side effects of Moderna [19-22]. The widely reported abnormalities were secondary immune secondary immune thrombocytopenia, immune thrombotic thrombocytopenic purpura, autoimmune hemolytic anemia, Evans' syndrome, and VITT [23, 32, 33, 34, 35, 26]. Although the severity of complication is limited, there could be complication enough severe leading to death [22]. This paper aims at determining the abnormalities faced by Indian population after the last dose of all vaccines listed above. In India, two vaccines were reported to have administered along with the ones listed above, they are COVIDSHIELD and COVAXIN [21, 34, 35, 36,37]. In this paper, we want to study the abnormalities found after COVID-19 vaccination using reliable government based real-world data [31], [32], [33], [34], [35], [36], [37].

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2 DATA AND METHODS USED

2.1 DATA SOURCE

India is a unique country and brings it owns benefits and challenges. India has a central public body called the national health authority which houses data from all over the regions in India. All this data is collected from Government Hospitals, clinics and hospital sites. It also collects data from private hospitals through which it has direct ties and funds some of the research at their facilities. From this data we randomly selected data for all those people living in New Delhi from January 2021 (a year prior) and obtained their diagnosis up until 2022 December if they had visited the same facility after the vaccine administration. Of the total of 11,341,189 only 8,782,149 were deemed as adults. There were patients whose age is not determined either because they did not have a government issued ID or did not have Birth certificate.

2.2 DATA METHOD

This study excluded patients who had just received only one dosage or had died after their first dosage or had preexisting conditions either primary or secondary. In India, everyone was tracked through a Mobile app which kept tab on the visits. So, any missing participants and who had not taken any vaccination as of December 2021 were excluded from the study. Diagnosis records in the year after 2021 were the only data used in this study.

2.3 DATA COLLECTION

Viral Vector Vaccines, mRNA vaccines and their subunits used in the vaccination procedure were included in this study. Sectors investigated this study included age, sex, Charlson Comorbidity Index (CCI), diabetes, hypertension, hyper lipidaemia, Chronic Obstructive Pulmonary disease (COPD) and COVID-19 infection in general were collected from the sample population. The diagnosis code for each CCI diseases listed was used [24]. Those who had each of the CCI diseases (Hypertension, hyper lipidemia, diabetes, and COPD) were tracked and were validated after all dosage of the vaccines were taken and in 2022-year window. From the sample, we wanted to study nutritional, hemolytic and aplastic anaemia, coagulation defects and neutropenia as abnormalities were taken into consideration along with their codes. The abnormalities were investigated in a 1 month, 6month and 1 year basis.

2.4 DATA SAMPLE

There was a total of 8,782,149 included in this study from the initial 11,341,189, as these were adults. Out of these adults only 8,942,409 had taken the complete second dosage of the vaccines by end of December 2021. The final study sample of vaccination excluded those who with other diseases and people who had only one dosage. Then there were people who had died, in India, since the national health authority does keep a track of the deaths, they will be clubbed along those who took only one dosage. The final number comes back as 6,023,134.

2.5 DATA TESTS

The analyses and data preparations were done using the SAS enterprise guide. There were different kinds of tests done on the data like Student's t-test to compare continuous variables and chi-square test or fisher's test to compare categorical variables. The incidence rate / 10000 person-years are also calculated. Regression model used were odd ratios (OR), confidence intervals (CI) and p-values. Cox regression model was used primarily for Hazard ratio, confidence interval and p-value calculations.

3 RESULTS

Table 1. Shows the breakdown of the sample data

	Total No	Vaccination No		P-Value
		No	Yes	
Total No	1,144,396.00	1144396	4878738	
Male	492090	83655	408435	<0.001
Female	652306	78276	574030	
Age, years, mean (SD)	52.87	44.31	53.42	< 0.001
18-29	134810	25614	109196	
30-39	122221	22000	100221	
40-49	144766	24610	120156	
50-59	188825	35121	153704	
>60	217435	38269	179166	
CCI				
0	789,633	118445	671188	
1	194547	36536	158011	
2	972737	170035	802702	
Comorbidity				
Diabetes	446314	49094	397220	< 0.001
Hyperlipidaemia	377651	52871	324780	< 0.001
Hypertension	310131	37216	272915	< 0.001
COPD	68664	7553	61111	< 0.001

Table 1 shows the demographics of the data sample. The vaccination rates were about 84% with more women surprisingly outdoing the men at 44%. The mean age of the data sample was 46, a relatively young age. The vaccination and non-vaccination mean age were 49 and 54 respective with a p<0.001. Individual in the age group of 50 and above had greater vaccination rates than the others. Those with CCI in 0, 1, and 2 had vaccination rates of 82%, 84% and 87% respectively. the data sample also looked at Comorbidities too, among patients with preexisting conditions like diabetes, hypertension, hyperlipidaemia, and COPD, there vaccination rates, 91%, 88%, 94% and 77%. India is known to be a diabetic capital of the world but patients with diabetes were vaccination more than people with hypertension.

3.1 ABNORMALITIES IN PATIENTS AFTER COVID-19 VACCINATION

3.1.1 NUTRITIONAL AMENIA

From the data, when we looked at vaccinated and non-vaccinated patients, the rate of nutritional anaemia at 1 month, 6 month and a year were 1.26 vs 0.73 (p=0.006); 8.31 vs 5.23 (P <0.001) and 17.23 vs 12.53 (p < 0.001). There were other regression tests done on the covariates which showed that the vaccination significantly increased the nutritional anaemia during the course of time in the entire year after the vaccination was administers with highest being 6 months after the vaccination where the ORs were 1.802 [94 CI, 120-4.21, p <.001]. Compared to the non-vaccinated group, the nutritional anaemia was not present leading to the HR of 1.601 (95% CI, 1.89 - 1.93, p < 0.001] and this is consistent amongst 70- 80% of the non-vaccinated patients.

Table 2. Nutritional Amenia

Disease	Variable	Value	HR	95% CI	P-Value
Neutropenia	Vaccine	No			
		only mRNA	0.948	05343 - 1.49	0.89
		Only vial vector	1.119	0.732 - 1.892	0.682
		Cross Vaccine	1.023	0.234 - 2.342	0.899
	sex	Female	2.693	1.972-4.5872	<0.001
	Age		0.892	0.934 - 1.012	0.7923
	CCI	0			
		1	1.28	0.742 - 2.793	0.356
		2	2.6874	1.694 - 4.524	<0.001
	Comorbidity	Diabetes	0.5	0.264 - 0.879	0.031
		Hypertension	0.86	0.621 - 1.454	0.437
		Hyperlipidaemia	0.972	0.682 - 1.8767	0.556
		COPD	0.772	0.552 - 8.779	0.241

Tableau 1. Regression Analysis

Disease	Reference	Values	OR	95%CI	P-value
Nutritional Anaemia	Viral Vector Vaccine	mRNA vaccine	1.23	1.132 - 1.313	< 0.001
	mRNA vaccine	Cross vaccine	1.18	0.893 - 1.32	0.23
	Viral vector vaccine	Cross vaccine	1.234	1.132 - 1.423	<0.001
Hemolytic Anaemia	Viral Vector Vaccine	mRNA vaccine	3.11	0.672 - 12.42	1.762
	mRNA vaccine	Cross vaccine			
	Viral vector vaccine	Cross vaccine			
Aplastic Anaemia	Viral Vector Vaccine	mRNA vaccine	1.212	1.131 - 1.33	< 0.001
	mRNA vaccine	Cross vaccine	0.932	0.632 - 1.037	0.184
	Viral vector vaccine	Cross vaccine	1.02	0.83 - 1.231	0.324
Coagulation defects	Viral Vector Vaccine	mRNA vaccine	1.042	0.923 - 1.213	0.29
	mRNA vaccine	Cross vaccine	1.031	0.682 - 1.313	0.789
	Viral vector vaccine	Cross vaccine	1.083	0.789 - 1.380	0.532

Nutritional anaemia increased dramatically after the mRNA vaccination than the viral vector vaccination. There was also a significant difference in the risk of Nutritional anaemia between the mRNA and cross-vaccination. The risks were further increase in the group of cross vaccination when compared earlier ((OR 1.323, 95% CI 1.142-1.345, P<.001).

3.1.2 Hemolytic Amenia

Hemolytic anaemia in the 6-month following the COVID-19 vaccine was 7 - 10 in the non-vaccinated and vaccinated patients with p<0.0007. The risk of hemolytic anaemia at the start of the vaccine administration decreased in both the mRNA (Hr 0.211, 95% CI 0.424 - 0.592, p - 0.004) and viral vector vaccination groups (HR 0.068, 95% CI 0.014-0.335, P=.001) significantly compared to the nonvaccinated group. There was absolutely no difference in the hemolytic anaemia between mRNA and viral vector vaccine groups. Age played a role in this observation with (HR, 1.047; 95% CI, 1.012-1.083; P=.008) significantly increased hemolytic anaemia as patients age grew.

3.1.3 Aplastic Amenia

We observed that the rate of aplastic anaemia in vaccinated and nonvaccinated groups where 0.8 and 0.39 (p=0.23), 2.90 vs 1.69 and 7.324 vs 5.234 (p < 0.001) at 1st month, 6 months and a year later. The risk of aplastic anaemia increased after the 1st month compared to nonvaccinated groups. The risk of aplastic anaemia increased too in the mRNA group (HR 1.394, 95% CI 1.183-1.643, P<0.001). Compared to the viral vector vaccine group, the mRNA vaccine group had significantly increased risk

too (OR 1.242, 95% CI 1.110-1.390, P<.001). The risk also increased with age with HR 1.012, 95% CI 1.007-1.071, P<.001) or in women (HR 1.520, 95% CI 1.334-1.733, P<.001) with females at a higher risk than males.

3.1.4 COAGULATION DEFECTS

Coagulation defects were found more in vaccinated versus nonvaccinated groups at 0.84 vs 1.31 (p< 0.001); 2.44 vs 0.42 (p < 0.001) and 4.79 vs 1.97, p < 0.001 at 1 month, 6 months and 1 year respectively. The risk of coagulation increased too with time, with the highest being at 1.898 (95% CI, 1.34 - 2.452, p = 0.005) while the lowest was found at 1st month with ORs 5.717 [95% CI, 2.10-15.53, P=.005] when compared to nonvaccinated patients' sample. The risk of coagulation also increased in mRNA and viral vector vaccines groups with the highest being the Modena vaccine with (HR 2.021, 95% CI 1.542-2.648, P<.001). As with other anaemia, females, older patients showed a greater risk of coagulation defects more and patients with diabetes for some reason shows lesser risk of coagulation defects.

4 DISCUSSION

This paper showed many abnormalities which were observed in the patients after the COVID-19 vaccination was administered. Cumulative rate of nutritional, aplastic anaemia and coagulation defects increased dramatically after a 6-month period and were found to profound after a year. In this paper, we looked at vaccines which increased the nutritional anaemia, and we found that mRNA vaccine tended to drive a higher risk for patients than viral vector vaccines. Cross-vaccination significantly increased the risk of nutritional anaemia compared to exclusive vaccine vaccination. We strongly recommend not to go with cross-vaccination ever in the future as it mostly tends to bring more risks. The study points that the mRNA drives the risk of nutritional anaemia higher than the rest.

Aplastic anaemia was also found to be higher in mRNA administered vaccine and not with viral vector vaccine. There have been other studies where it showed the other way, Aplastic anaemia was found to be higher in viral vector vaccines [25]. In this study, the risks of nutritional and aplastic anaemia were higher in mRNA vaccine group. The hemolytic anaemia was also found to more than viral vector vaccines and these findings are supported by other studies conducted earlier [13, 14]. These studies conclude that the mRNA was a risker vaccine than the viral vector types [6, 7, 9, 10, 12, 15-17, 19-21].

Coagulation defects increased both in the mRNA as well as viral vector vaccines, with minor difference that are miniscule to report. There are studies which reported COVID-19 vaccination [17, 23, 26] especially the mRNA vaccines [17, 23, 26] increased the hemolytic anaemia but our study did not see any such drastic increase when it came to hemolytic anaemia. Further research is needed to conclude here.

The results of this paper are based on data from India Health Authority where data is taken from patients from New Delhi, however, pathophysiologic process underlying the correlation between vaccines and side effects could not be determined and was not in the scope of this paper. However, it looks likes the type of vaccine and the duration of the vaccines in patients body point to the connection. We think, we need to be careful in bringing to the attention when administering COVID-19 vaccines to people with preconditions. Especially elder and pregnant people whose underlying diseases need careful consideration before the vaccine is administered.

5 CONCLUSION

In this paper showed from the analysed data that Nutritional anaemia, Aplastic anaemia and coagulation defects increased dramatically after the COVID-19 vaccination. So did the nutritional anaemia, which had a direct correlation with the mRNA vaccine administration. Aplastic also increased when the patients took mRNA related vaccines but not the viral vector vaccines, however there are studies which showed otherwise, so we do not want to conclude anything on Aplastic anaemia and mRNA vaccine correlation. There are other risk factors for older and females which showed aplastic and nutritional anaemia at a greater risk than any age groups. Although the sample size is large, we think further research is needed to investigate these abnormalities based on the type of vaccine used and the length of the time after the vaccine is administered.

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