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Three Year Study of Covid and Covid Vaccine Induced Thrombosis in Indian Patients

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ABSTRACT
To assess covid and covid vaccine induced thrombosis in Indian patients. One hundred ten subjects who received COVID-19 vaccine of both genders were included. Parameters such as vaccination history, clinical presentation, treatment administered and vaccine type and dosage, length of time from vaccination date to onset of neuropsychiatric symptoms, clinical manifestations, results of neuro-imaging, treatment administered, and outcome were recorded. Out of 110 subjects, males were 50 (45.4%) and females were 60 (54.6%). 23 males and 30 females developed COVID-19 infection. The vaccine type used in subjects was Covishield in 50 and Covaxin in 60. The on set of adverse events after vaccination (in days) after first dose (mean) was 12.4 days and after second dose (mean) was 10.5 days. Adverse events reported were facial diplegia and bulbar palsy in 11, inflammatory myositis in 4 and herpes zoster in 3 patients. COVID-associated thrombosis was reported in 24 patients. Neuro-imaging revealed thrombosis in left transverse sinus in 7, sigmoid sinuses in 5 and superior sagittal sinus in 12 patients. Treatment given was Methyl prednisolone in 7, Plasmapheresis in 6, Mycophenolate mofetil in 4 and Rituximab in 7 patients. Outcome was improvement in 16 and death in 8 cases. The difference was significant ($p<0.05$). Numerous severe neurological side effects have been documented in Indian recipients of the COVID-19 vaccination. The most common was COVID associated thrombosis. Neuro-imaging revealed thrombosis in left transverse sinus, sigmoid sinuses and superior sagittal sinus.

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Key Words
COVID-19, plasmapheresis, rituximab, superior sagittal sinus

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INTRODUCTION

The COVID-19 pandemic has spread quickly after the first cluster of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was discovered in Wuhan, China in December 2019, overwhelming medical systems all over the world[1]. As of August 13, 2021, records worldwide included more than 205,338,159 confirmed cases and 4,333,094 deaths[2]. To put the magnitude into perspective, consider that more people have died from COVID-19 than have from influenza in the century since the previous pandemic[3].

On January 18, 2021 the coronavirus disease 2019 (COVID-19) vaccination campaign was launched in India[4]. According to the Government of India-owned COWIN (Covid Vaccine Intelligence Network) platform, 1,97,34,08,500 vaccination doses had been given as of June 28, 2022, with the COVISHIELDTM vaccine accounting for the majority of them. The COVID-19 vaccine may cause a variety of unfavorable side effects[5]. Adverse effects following immunization that are frequently reported include headache, dizziness, fever, chills, myalgia, arthralgia, injection site discomfort and tenderness, fever, nausea and vomiting. These negative occurrences are modest and self-limiting[6].

Following the injection of adenoviral vector-based vaccines, vaccine-induced thrombosis and thrombocytopenia (VITT) frequently present as potentially fatal cerebral venous sinus and splanchnic artery thrombosis[7,8]. Numerous accounts have detailed demyelinating diseases of the central nervous system (CNS) after receiving the COVID-19 vaccine. Several individuals have also reported experiencing post-vaccinal psychiatric adverse effects, including transitory global amnesia and functional neurological disorders (FNDs)[9]. We performed this study to assess covid and covid vaccine induced thrombosis in Indian patients.

MATERIALS AND METHODS

After considering the utility of the study and obtaining approval from ethical review committee, we selected one hundred ten subjects who received COVID-19 vaccine of both genders. Patient's consent was obtained before starting the study. Data such as name, age, gender etc. was recorded. Parameters such as vaccination history, clinical presentation, treatment administered and vaccine type and dosage, length of time from vaccination date to on set of neuropsychiatric symptoms, clinical manifestations, results of neuroimaging, treatment administered and outcome were recorded. The results were compiled and subjected for statistical analysis using Mann Whitney U.test $p<0.05$ was set significant.

RESULTS

Out of 110 subjects, males were 50 (45.4%) and females were 60 (54.6%). 23 males and 30 females developed COVID-19 infection (Table I). The vaccine type used in subjects was Covishield in 50 and Covaxin in 60. The onset of adverse events after vaccination (in days) after first dose (mean) was 12.4 days and after second dose (mean) was 10.5 days. Adverse events reported were facial diplegia and/or bulbar palsy in 11, inflammatory myositis in 4 and herpes zoster in 3 patients. COVID-associated thrombosis was reported in 24 patients. Neuro-imaging revealed thrombosis in left transverse sinus in 7, sigmoid sinuses in 5 and superior sagittal sinus in 12 patients. Treatment given was Methyl-prednisolone in 7, Plasmapheresis in 6, Mycophenolate mofetil in 4 and Rituximab in 7 patients. Outcome was improvement in 16 and death in 8 cases. The difference was significant ($p<0.05$) (Table. 2, Fig. 1).

DISCUSSIONS

The vaccine COVISHIELD is a chimpanzee adenovirus vector-based recombinant vaccine that lacks replication and encodes the SARS-CoV-2 Spike (S) glycoprotein[10]. The Oxford-Astra Zeneca created it and the Serum Institute of India (SII) is producing it domestically[11-13]. India's domestic COVID-19 vaccine, COVAXIN, is an inactivated whole-virion vaccine that was created by Bharat Biotech, the National Institute of Virology (NIV), and the Indian Council of Medical Research (ICMR)[14-16]. We performed this study to assess covid and covid vaccine induced thrombosis in Indian patients.

Out of 110 subjects, males were 50 (45.4%) and females were 60 (54.6%). 23 males and 30 females developed COVID-19 infection. Garg *et al*.[17] in their study a total of 64 documents detailing 136 cases of severe adverse effects related to the nervous system and psyche were found. The following four states accounted for more than half of the reports (36 out of 64): Kerala, Uttar Pradesh, New Delhi, and West Bengal. The average age of individuals experiencing these issues was 44.89±15.77 years. The bulk of adverse events happened within two weeks after the COVISHIELD vaccine's initial dosage. 54 cases of immune-mediated diseases of the central nervous system (CNS) were found. There have been 21 cases documented of immune-mediated peripheral neuroopathies, including Guillain-Barre syndrome. Thirty-one vaccine recipients developed post-vaccinal herpes zoster. Six patients had psychiatric adverse effects documented. Numerous severe neurological side effects have been documented in Indian recipients of the COVID-19 vaccination. In our study, the vaccine type used in subjects was Covishield in 50 and Covaxin in 60. The onset of adverse events after vaccination (in days) after first dose (mean) was 12.4 days and after second dose (mean) was 10.5 days. Adverse events reported were facial diplegia and bulbar palsy in 11, inflammatory myositis in 4 and herpes zoster in 3 patients. COVID-associated thrombosis was reported

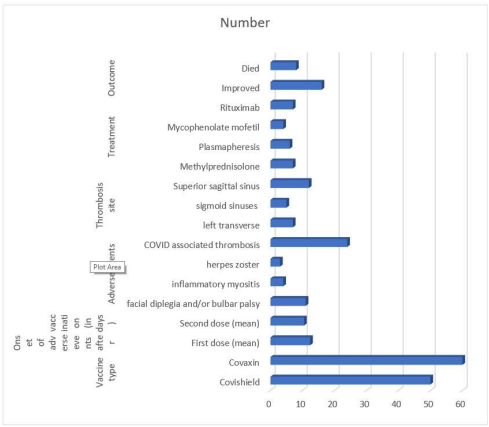

Fig. 1: Assessment of parameters

Table 1: Patients distribution

Total- 110

Gender	Males	Females
Number (%)	50 (45.4%)	60 (54.6%)
Patients developed COVID-19 infection	23	30

Table 2: Assessment of parameters

Parameters	Variables	No.	p-value
Vaccine type	Covishield	50	0.81
	Covaxin	60	
Onset of adverse events after vaccination (in days)	First dose (mean)	12.4	0.04
	Second dose (mean)	10.5	
Adverse events	facial diplegia and bulbar palsy	11	0.05
	inflammatory myositis	4	
	herpes zoster	3	
	COVID associated thrombosis	24	
Thrombosis site	left transverse	7	0.25
	sigmoid sinuses	5	
	Superior sagittal sinus	12	
Treatment	Methylprednisolone	7	0.94
	Plasmapheresis	6	
	Mycophenolate mofetil	4	
	Rituximab	7	
Outcome	Improved	16	0.03
	Died	8	

in 24 patients. Neuro-imaging revealed thrombosis in left transverse sinus in 7, sigmoid sinuses in 5 and superior sagittal sinus in 12 patients. Treatment given was Methyl-prednisolone in 7, Plasmapheresis in 6, Mycophenolate mofetil in 4 and Rituximab in 7 patients. The outcome was improvement in 16 and death in 8 cases. Guditi *et al.*[18] reported a case in which extensive cerebral venous thrombosis, right frontal hemorrhage, surrounding perilesional edema, mass effect, midline shift and intra-ventricular hemorrhage were all observed in the neuro-imaging investigations. The results showed that the patient had anemia with hemoglobin levels between 12 and 15 g dL^{-1}, leukocytosis with total leukocyte counts between 4,300 and 10,800 mm3, thrombocytopenia with platelet counts between 50,000 and 450,000 mm3, folate levels between 3.5 and 38.52 nmol L, and vitamin B12 deficiency between 37 and 118 pmol L. Prothrombin time 15 seconds, international normalized ratio 1.5, plasma fibrinogen 250 mg dL^{-1} and the renal and liver function tests (urea 45 mg dL^{-1}, creatinine 1.2 mg dL^{-1}, aspertate amino-transferase 45 U L^{-1}, alanine amino-transferase 35 U L^{-1} and alkaline phosphatase 170 U L) were all within normal ranges.

CONCLUSION

Numerous severe neurological side effects have been documented in Indian recipients of the COVID-19 vaccination. The most common was COVID associated thrombosis. Neuro-imaging revealed thrombosis in left transverse sinus, sigmoid sinuses and superior sagittal sinus.

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