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Self reports of post-vaccination outcome by COVID-19 vaccine recipients across various study settings: An electronic survey

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Abstract---Background India rolled out its vaccination program against COVID 19 on and from 16th January 2021. Apart from preventive measures like Covid Appropriate Behavior, vaccines were introduced as key specific protection against the virus in several parts of world. The present study is designed to profile spectrum of post vaccination outcome in terms of clinical signs/symptoms including adverse effects encountered among recipients across India. Methods: An online cross-sectional survey was conducted among 188 vaccine recipients of more than 18 years of age through snow ball sampling using a semi- structured, pre tested instrument with appropriate questions after taking informed consent. Results: In this study 12.7 % were found to have tested positive for COVID-19 and 28.7 %were having various co-morbidity. Among all co-morbidities hypertension, diabetes and obesity were statistically significant with Covid status of the patients. 'Pain at injection site' was the most common symptom observed among Covid-19 positive and negative groups. A significant

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difference was observed between proportions of recipients with 'fever', 'chills' and 'fatigue' implying an association between test status for Covid and the symptoms. Within first 24 hours, 38.5% people had experienced 'arthralgia' and 71% of the people had reported 'pain at injection site'. Upto 24 hours, 'breathing difficulty' was observed in 50% of recipients and 'pain at injection site' lasted for upto 72 hours in 83 % of recipients. Most of the symptoms lasted for a week except for 'breathing difficulty' and 'palpitation'. Conclusion: The study finding may help standardize & profile post vaccination outcome across varied study settings.

Keywords--COVID-19, post-vaccination, co-morbidity.

Introduction

The novel corona virus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome corona virus 2 (SARS-CoV-2), originated from Wuhan, China and was first identified in December 2019.[1]The virus speedily feasted globally within 3 months and as of March 11, 2020, was considered a global pandemic by the World Health Organization.[2] This outbreak was unique in terms compared to earlier corona viruses epidemic as it is highly pathogenic and causes high morbidity, the infected patients suffer from broad range of symptoms varying from cough, fever, shortness of breath requiring mechanical ventilation causing high mortality. [3,4,5] The early presentation of COVID-19 infection is typically non-specific. In different study settings, among symptomatic patients, about 80% showed a mild clinical course characterized by a dry cough, sore throat, low-grade fever, or malaise; in 20% of cases, after a duration of almost one week from the beginning of the symptoms the general condition of the patient deteriorates, culminating in respiratory failure [6,7].The epidemic has undergone a 2ndand 3rdresurgence due presumably to "risk compensation' by the community and emergence of more virulent, easily transmissible variants of concern precipitating rapid progression of the disease and escaping established immune competence either by previous infection or vaccination. As a part of control measures against COVID-19, vaccines have been rolled out in several parts of the world and India launched its vaccination drive since 16thJanuary, 2021[8]. Although vaccines are considered safe and their protective efficacy is well documented, due to novelty of the disease considerable knowledge gap still exists vis-à-vis real-world post-vaccination experience outside of clinical trial conditions.

Rationale

The present study is designed to profile spectrum of post vaccination outcome in terms of clinical signs/symptoms including adverse effects encountered among recipients across India which may help compare analogous initiatives and thus standardize post- vaccination outcome, inform & sensitize public, dispel misinformation and reduce vaccine hesitancy.

Materials and Methods

Study Design and Sampling method & sample size

We conducted an online cross-sectional survey among vaccine recipients i.e health workers/ professionals 18 years and above during two (02) weeks' period beginning February 15th, 2021.The online survey was conducted through Google form. Recruitment of study subjects i.e vaccine recipients was done by 'snowball' sampling and sampling took into consideration both '; purpose' & 'convenience' of operationalizing such an initiative. As it was not conducive & feasible to conduct a community-based survey across varied study settings in an ongoing pandemic situation, we decided to evaluate post- vaccination outcome of COVID-19 vaccine recipients using a web-based approach.

Implementation Plan

A semi- structured, pre tested instrument with questions appropriate to objectives of the study were drafted in Google form. The link of the Google form was sent/mailed to vaccine recipients i.e doctors/health workers essentially with established credentials, known and endorsed/authenticated by the contributors of the present study.

Apprising Study participants

The study participants/respondents whose age was more than 18 years and belonged to Indian nationality were instructed to fill the digital questionnaire, informed of the details of study objectives, procedures, average time taken for filling the questionnaire& confidentiality at the beginning of the survey and their informed consent in digital form was asked for participation in the study. The final sample comprised of 188 respondents.

Profiling study participants' pre- vaccination socio-demographics and clinical history

We asked recipients to report their age, gender, occupation and highest education or professional qualification. We also asked participants about status of COVID-19 infection, symptoms present, duration of the symptoms, severity of disease and co -morbidities, if there were any.

Post Vaccination Outcome

Post vaccination outcome considered were range, duration and persistence of symptoms, place of seeking treatment, duration of stay in a hospital, severity of disease, co-morbidities (Diabetes, Hypertension, Asthma/ COPD, Obesity, Heart Disease, Neurological Disorders and Malignancies), untoward response including allergic/ hypersensitivity reaction previously to any vaccination/ product of injectable medication, source of information about COVID 19 vaccine, type of vaccine received, discomfort/ difficulty after medication, medication taken to relieve symptoms post vaccination, difficulty in daily activities post vaccination etc.

Observation

All data on personal demographics (age groups, gender, highest educational level, occupation, presence of co-morbidities and status of COVID-19 infection) were categorically expressedas counts and percentages of total respondents. Data on source of information aboutCOVID-19 vaccine, symptoms of PostCOVID-19 vaccinationwere also expressed as counts and percentages of total respondents. Sub-group categorical analyses were conducted to examine the side effects of vaccination by test positivity and co- morbidities. Proportion of testing was done using *z* test for proportions.

Results

Out of a total of 192 subjects who were approached, 188 completed the online survey yielding response rate of 97.9%. Of the 188 eligible recipients, 83 (44.1%) of the respondents were male and 132(70.2 %) were well educated with a Bachelor's degree or above.The mean age of all recipients were found to be 41.79±12.39 (Table 1). Table 2 reveals the distribution of vaccine recipients by co-morbidities and test positivity. Out of 188 recipients, 54(28.7 %) were co-morbid with any or the other morbidity and 24(12.7%) were found to have tested positive for COVID -19. For all co-morbid recipients evaluatedi.e54 (28.7%), 12(22.2 %)recipients were test positive while among non co-morbid recipients i.e.134 (71.2%), the corresponding proportion was also 12(8.9%);as many as 122 (91%) among non co-morbid recipients were Covid negative. A statistically significant association between co-morbidity and Covid status of recipients can be observed from Table-3.Significant differences in proportion of recipients with or without Covid, evident in cases of hypertension (p=0.05) diabetes (p=0.00) & obesity (p= 0.001) and those with non co -morbidity (p=0.01) were observed or in other words, the aforesaid conditions were significantly associated with Covid status of the recipients.

Table 4 reveals distribution of common symptoms after vaccination according to test status for COVID. 'Pain at injection site' was the most common symptom between the groups. A significant difference was observed between proportions of recipients with fever, chills and fatigue implying an association between test status for Covid and the symptoms i.e 'fever', (p=0.025), 'chills' (p= 0.018) and 'fatigue' (p= 0.05). Table 5 represents the time of appearance of symptoms among recipients. For most of the symptoms, proportion of people in whom symptoms

appeared in less than 24 hours seemed to be higher than those who got symptoms after 24 hours except for people who experienced arthralgia. Percentage of people who experienced arthralgia in less than 24 hours was just 38.5%.Seventy one percent (71%) of the people reporting pain at injection site had experienced it within the first 24 hour. It can be seen from Table 6that the duration of post vaccination symptoms for most of the symptoms was upto one week (07 days) except in cases of 'breathing difficulty' and 'palpitation'. As many as fifty percent (50 %) of the recipients had 'breathing difficulty' followed by 'chills' (48 %), 'palpitation' (43%), 'malaise' (41%) and 'fever' (34 %) upto 24 hours. 'Pain at injection site' lasted upto72 hours for 83% of recipients; 40 % of recipients each for 'fever' and 'fatigue' had these symptoms lasting upto 48 hours.

Discussion

The immunity of the community as a 'herd' is supposed to get re-enforced by the day with an ongoing vaccination drive. In view of this, the relevance of the present study i.e profiling post vaccination outcome across different study settings attains much importance. As one of the largest vaccination drives that the world has known yet, our country continues to bear considerable 'vaccine hesitancy' vis- a vis COVID-19. Standardization of comprehensive data involving reliable samples across study settings of post vaccination outcome including on 'adverse effects following immunization' (AEFI) is a priority need. The present study describes the experiences by the vaccine recipients immediately and upto one week of receipt of vaccines. Male female differential among the study participants was not much, 44.1% of the respondents were male: 70.2% were well educated with bachelor's degree or above and mean age of the recipients was 41.79±12.39. Analogous studies by Danabal et al (37.1%) have comparable participant profile. [9]

Findings from the present study reveal that 54 (28.7%) of the recipients were co-morbid with any or the other co-morbidity and 12.7 % of them had tested Covid-19 positive: of the total co-morbid recipients i.e 54 (28.7%), 12 (22.2%) of the recipients were test positive and corresponding proportion among non-co-morbid recipients i.e 134 (71.2%) was 12 (8.9%): as many as 122 (91%) among non co-morbid recipients were Covid negative. Statistically significant association between co-morbidities and Covid status of the recipients was observed with significant differences in proportion of recipients with or without Covid evident in cases of hypertension, diabetes, obesity and those with non co-morbidity.Studies done by Wu Z et al and Wang A et al had found the similar results stating the disease's (COVID 19) severity and Case fatality both are high in persons with co-morbidities [10,11].

A significant association between test status for Covid and the symptoms i.e fever, chills and fatigue was also observed. "Pain at injection site" was found to be the most common symptom between the groups i.e those who tested positive& negative for Covid andthe time of appearance of this symptom for most of the recipients was less than 24 hours; also, "pain at injection site" lasted upto 72 hours for most of the recipients. Similar finding were reported by Sah R in a study done in Nepal where the sample size was relatively more. [12] This was true for most of the recipients i.e symptoms appeared in less than 24 hours except for those with arthralgia. Most of the symptoms in the present study lasted for upto a

week i.e 7 days except in cases of breathing difficulty and palpitation. About half of the recipients had breathing difficulty and chills. Studies done by Shrivastava et al, Ella R et al and Kakkar A et al had comparable finding findings related to the side effects of the vaccine. [13, 14, 15]

Limitation

Study is limited by its sample size, eliciting data in virtual mode and self appraisal by the participants.

Author's Contribution

Concept & Design- Dr. Debabrata Roy,
Definition of intellectual content & literature search- Dr. Richa Sinha,
Statistical Analysis- Dr. Sonam Maheshwari
Manuscript Preparation, editing and submission- Dr. Priyanka Dobhal
Manuscript Review: All Authors

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Conflict of interest: None

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Table 1
Distribution of Vaccine Recipients by Socio-Demographics (N=188)

Characteristics	Number (%)
Age	41.79±12.39
Gender	
Male	83(44.1)
Female	105(55.9)
Occupation	
Professional	89(47.3)
Semi professional	55(29.2)
Semiskilled worker	18(9.6)
Skilled worker	12(6.3)
Unskilled worker	14(7.4)
Education	
Upto primary	2(1.06)
Upto Secondary	17(9.04)
Upto Senior Secondary	20(10.6)
High School	17(9.0)

Graduate	25(13.3)
Post Graduate	66(35.1)
Professional	41(21.8)

Table 2
Distribution of vaccine recipients by comorbidities and test positivity (n=188)

Presence of Co-morbid Conditions	No (%) n=188	COVID-19 positive No (%) n=24	COVID-19 negative No (%) n=164	p -value
None	134(71.28)	12(50.00)	122(74.39)	0.013
Obesity	8(4.26)	4(16.67)	4(2.44)	0.001
Asthma/ COPD	4(2.13)	0(0.00)	4(2.44)	0.439
Diabetes	18(9.57)	8(33.33)	10(6.10)	0.000
Hypertension	24(12.77)	6(25.00)	18(10.98)	0.054
Thyroid	16(8.51)	2(8.33)	12(7.32)	0.859
Sarcoidosis	1(0.53)	0(0.00)	1(0.61)	0.701
Inflammatory Bowel Syndrome	1(0.53)	0(0.00)	1(0.61)	0.701

Table 3
Distribution of Recipients by COVID Status & Co-morbidity (n= 188)

Co-morbidity Status	No (%) n=188	COVID-19 positive No (%) n=24	COVID-19 negative No (%) n=164	p -value
No Co-morbidity	134 (71.27)	12 (50)	122 (74.39)	0.000
Co-morbidity	54 (28.72)	12 (50)	42 (25.60)	

Table 4
Distribution of vaccine recipients by symptoms and test positivity

Common Symptoms post Vaccination	No (%) n=188	COVID-19 positive No (%) n=24	COVID-19 negative No (%) n=164	p -value
Fever	70(37.23)	4(16.67)	66(40.24)	0.025
Chills	54(28.72)	2(8.33)	52(31.71)	0.018
Malaise	58(30.85)	4(16.67)	54(32.93)	0.107
Myalgia	46(24.47)	4(16.67)	42(24.47)	0.341
Arthralgia	26(13.83)	2(8.33)	22(13.41)	0.486
Fatigue	64(34.04)	4(16.67)	60(36.59)	0.054
Breathing Difficulty	20(10.64)	2(8.33)	18(10.98)	0.694
Palpitation	42(22.34)	2(8.33)	40(24.39)	0.077
Pain at Injection Site	82(43.62)	8(33.33)	74(45.12)	0.277

Table 5
Distribution of vaccine recipients by time of appearance of symptoms

Common Symptoms post Vaccination	n=188 N (%)	Symptoms appear				
		Immediately (within 8 hrs) N (%)	≤ 24 hours N (%)	24-48 hours N (%)	48-72 hrs hours N (%)	Up to 1 week N (%)
Fever	70 (37.23)	4 (5.7%)	39 (55.7%)	18 (25.7%)	2 (2.9%)	6 (8.6%)
Chills	54 (28.72)	4 (7.4)	38 (70.4)	6 (11.1%)	2 (3.7%)	4 (7.4%)
Malaise	58(30.85)	6 (10.3%)	30 (51.7%)	12 (20.7%)	4 (69%)	6 (10.3%)
Myalgia	46(24.47)	4 (8.7%)	22 (47.8%)	10 (21.7%)	6 (13%)	4 (8.7%)
Arthralgia	26(13.83)	4 (15.4%)	6 (23.1%)	6(23.1%)	6 (23.1%)	4 (15.4%)
Fatigue	64(34.04)	4 (6.3%)	38 (59.4%)	14 (21.9%)	4 (6.3%)	4 (6.3%)
Breathing Difficulty	20(10.64)	4 (20%)	6 (30%)	0(0.0%)	6 (30%)	4 (20%)
Palpitation	42(22.34)	2 (4.8%)	28 (66.7)	2 (4.8%)	6 (14.3%)	4 (9.5%)
Pain at Injection Site	82(43.62)	8 (9.8%)	50(61 %)	16 (19.5%)	4 (4.9%)	4 (4.9%)

Table 6
Distribution of recipients by duration of presence of symptoms (n=188)

Common Symptoms post Vaccination	n=188 N (%)	Duration of Symptoms			
		≤ 24 hours N (%)	24-48 hours N (%)	48-72 hrs hours N (%)	Up to one week N (%)
Fever		24 (34.29)	28(40.00)	12(17.14)	6(8.57)
Chills	70 (37.23)	26(48.15)	16(29.63)	10(18.52)	2(3.70)
Malaise	54 (28.72)	24(41.38)	20(34.48)	8(13.79)	6(10.34)
Myalgia	58(30.85)	12(26.09)	16(34.78)	14(30.43)	4(8.70)
Arthralgia	46(24.47)	6(23.08)	10(38.46)	8(30.77)	2(7.69)
Fatigue	26(13.83)	20(31.25)	26(40.63)	16(25.00)	2(3.13)
Breathing Difficulty	64(34.04)	10(50.00)	4(20.00)	6(30.00)	0(0.00)
Palpitation	20(10.64)	18(42.86)	13(31.0)	11(26.10)	0(0.00)
Pain at Injection Site	42(22.34)	10(12.20)	34(41.46)	34(41.46)	4(4.88)

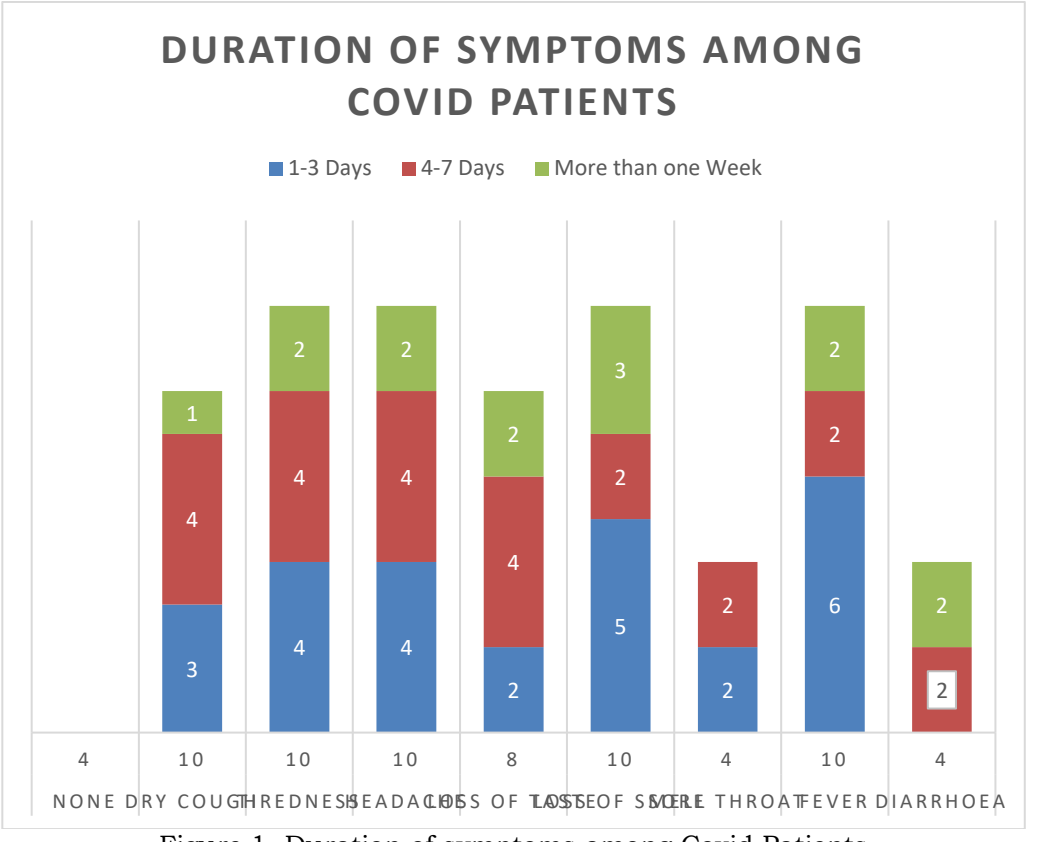

Figure 1. Duration of symptoms among Covid Patients