Short Paper



Assessment of psychological distress pattern & its correlates among people receiving COVID-19 vaccination during the COVID-19 pandemic: A cross-sectional study

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Background & objectives: There is a possibility that vaccinated people may experience lesser psychological distress due to the sense of safety felt by them against getting the COVID-19 infection as compared to those who are not vaccinated. However, there is a paucity of research examining the mental health status of this important sub-group of population. Thus, the present study was aimed to examine the pattern of psychological distress and its correlates among people receiving COVID-19 vaccine.

Methods: This cross-sectional study assessed individuals receiving COVID-19 vaccine at a tertiary care hospital. Psychological distress and COVID-19-related anxiety were assessed using the Depression Anxiety Stress Scale (DASS-21) and the COVID-19 Anxiety Scale-7, respectively.

Results: The study comprised 728 individuals with a mean age of 44.8 yr. Moderate levels of depression, anxiety and stress were reported by about 50, six and 15 per cent of the participants, respectively, as assessed on DASS-21. Generalized linear model and quantile regression analyses revealed COVID-19-related anxiety, and being a healthcare worker or front-line worker as significant correlates of psychological distress.

Interpretation & conclusions: About half of the study participants receiving COVID-19 vaccine reported moderate to severe symptoms of depression. Strategies focusing on alleviation of COVID-19-related fear and anxiety might be effective in improving the symptoms of psychological distress.

Key words COVID-19 anxiety - depression - DASS-21 - mental health - stress

India has been among the worst affected countries by the second wave of the COVID-19 pandemic in terms of the total number of cases and deaths due to COVID-19¹. The public health policy decision of implementing lockdown and quarantine by various governments to control the rapid spread of the COVID-19 pandemic was necessary, though associated with adverse psychological effects².

A meta-analysis of studies assessing the mental health effects of the COVID-19 pandemic from different countries reported prevalence of depression, anxiety and stress at 33.7 [95% confidence interval (CI): 27.5-40.6], 31.9 (95% CI: 27.5-36.7) and 29.6 per cent (95% CI: 24.3-35.4), respectively³. These rates were comparable to the reported prevalence of depression (41.9%; 95% CI: 29.1-54.6), anxiety (42.8%; 95% CI: 30.2-55.4) and stress (58.0%; 95% CI: 44.8-71.2) in another meta-analysis of studies exclusively conducted among healthcare professionals from India⁴. However, almost all these studies were conducted when no vaccine or specific treatment was available for COVID-19, and the only ways to control the pandemic were to follow personal precautions such as wearing facemasks, hand hygiene at the individual level and restricting physical movements and socialization (e.g. closure of restaurants, shutting down non-essential services) at the community level.

It could be possible that vaccinated people might experience less psychological distress due to the sense of safety felt by them against COVID-19 infection. However, this area of research has not been explored much. The present study was thus planned to assess the mental health of people receiving COVID-19 vaccine during the COVID-19 pandemic in India. It was also aimed to examine the pattern of psychological distress and its demographic and clinical correlates among people receiving COVID-19 vaccine.

Material & Methods

A cross-sectional exploratory study was conducted at the COVID vaccination Centre (CVC), All India Institute of Medical Sciences (AIIMS), New Delhi, India. Participants with age at least 18 yr, either gender and having received at least one dose of COVID-19 vaccine at the CVC were eligible to participate. Participants not able to complete self-report-based questionnaire due to any health condition or limited comprehension ability or not providing informed written consent were excluded from the study.

Study procedure: People receiving the COVID-19 vaccine at the CVC were approached for participation in the present study after they had received the vaccine and waiting for post-vaccination observation period of 30 minutes. Those who met the eligibility criteria were informed regarding the study objectives, duration of participation, declaration of confidentiality and voluntary participation before administration of the questionnaire. Subsequently, those who gave informed written consent were recruited by purposive sampling over a period of four weeks (June-July 2021). The data collection was carried out using online Google Form

for data entry in a single sitting. The study protocol was approved by the Institute Ethics Committee (IEC-343/04.06.2021).

A semi-structured proforma developed for this study was used to record details about the sociodemographic and relevant clinical characteristics of the study participants. Information collected included current living arrangement, education and occupational status, history of confirmed or suspected COVID-19 infection and presence of any known medical comorbidities (based on self-report).

The Depression Anxiety Stress Scale (DASS-21) was used to measure the negative emotional states of depression, anxiety and stress. DASS-21 has three sub-scales, each consisting of seven self-report-based questions⁵. Total score ranges between 0 and 63, with higher scores suggesting greater severity of symptoms. DASS-21 has well-established psychometric properties and has been previously used to assess psychological distress among the general population in Indian setting with good construct validity and internal consistency⁶.

COVID-19 Anxiety Scale (CAS-7) was used to assess COVID-related anxiety. CAS-7 consists of seven self-reported items that assessed cognitive, emotional and physiological dimensions of COVID-19-related anxiety. Total score ranges between 7 and 28, with higher scores suggesting greater COVID-19 anxiety levels⁷. CAS-7 has been developed to assess COVID-19 anxiety among the general population keeping in mind the Indian context, and the scale has demonstrated adequate face and content validity, structural validity, construct validity, internal consistency and test–retest reliability^{8,9}.

Statistical analysis: The data were analyzed using the SPSS Statistics for windows, version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics using mean, standard deviation (SD), frequency and percentage were used to describe the socio-demographic and clinical profile, CAS-7 score and DASS-21 score. In addition, median and interquartile range were described for skewed data. DASS-21 and CAS-7 scores remained significantly skewed even after attempting logarithmic transformation (checked using Kolmogorov-Smirnov and Shapiro-Wilk tests); and non-parametric tests were applied. Bivariate analysis using appropriate inferential statistics (Mann-Whitney U test, Kruskal-Wallis test and Spearman correlation) was conducted to examine associations between different variables and DASS-21 total or sub-scale scores. The linear relationship

between dependent and independent variables was tested by visual examination of corresponding scatter plots. Since the dependent/outcome variable of interest was not normally distributed, generalized linear model with gamma regression (gamma probability distribution and log link function) was carried out. All the variables having significant bivariate association with dependent variable (i.e. DASS-21 total score, or sub-scale scores) were entered as covariates or factors in the generalized linear model to determine the correlates of psychological distress. Further, quantile regression analyses were also conducted to test whether there was any significant difference in the correlates obtained from generalized linear model. This was done in view of quantile regression analysis being a more robust method when the data are not normally distributed and homoscedasticity of residuals cannot be ensured. Furthermore, quantile regression results are less affected by outliers in the data.

Results & Discussion

The study sample comprised 728 individuals with 57.4 per cent males and with a mean age of 44.88±14.15 years. Table I describes the sociodemographic and clinical profile of these individuals.

The severity distribution of depression, anxiety and stress symptoms among study participants based on DASS-21 sub-scale scores is described in Table II. About half of our study participants experienced moderate to extremely severe symptoms of depression. This was comparable with an estimate of 48.8 per cent as reported in another online surveybased study conducted among the general population in India during the second wave of COVID-19¹⁰, but more than 25 per cent reported in another online survey-based study conducted among the general population in India during the first wave of COVID-1911. However, 5.8 and 15.2 per cent of our study participants reported at least moderately severe symptoms of anxiety and stress, respectively, which was lesser than that reported in a previous study¹⁰. This could be due to the difference in sociodemographic characteristics of the study sample between these two studies. In addition, both these previous studies have been conducted in a convenience sample recruited online and might suffer from selection and measurement biases¹². Thus, the present study finding of at least moderately severe depressive symptoms in about half of the people receiving COVID-19 vaccine is alarming.

The relationship between psychological distress and COVID-19-related anxiety, socio-demographic and clinical profile was assessed using bivariate analysis. CAS-7 scores showed a positive correlation with stress (r = 0.44, P < 0.01), anxiety (r = 0.36, P < 0.01), and depression (r=0.19, P<0.01) sub-scale scores of DASS-21. There was a significant positive correlation between CAS-7 and DASS-21 scores (r = 0.56, P < 0.01); whereas a small but significant negative correlation was observed between age and DASS-21 score (r_e=-0.08, P=0.02). Scores on DASS-21 were significantly greater for healthcare workers (HCWs) and frontline workers (FLWs) [median score=32.00, Interquartile range (IQR): 25.00-38.00] than for people of other occupations (median score=30.00, IQR: 24.00-34.00; U=71070.50, P=0.01). People with comorbid diabetes mellitus (median score=32.00, IQR: 26.00-42.00) had significantly greater DASS-21 scores as compared to the rest of the study participants (median score=30.00, IQR: 24.00-36.00; U=32529.50, P<0.01). There was no significant association between DASS-21 scores and other study variables examined. Further, bivariate analyses were carried out to determine the relationship between the three different DASS-21 sub-scale scores (i.e. depression, anxiety and stress) and COVID-19related anxiety, sociodemographic and clinical profile (Table III).

A generalized linear regression model was constructed with all the variables that showed a significant relationship with mental well-being in the bivariate analysis. These variables were entered as independent variables or covariates in the model, and the DASS-21 score was entered as the dependent variable. The model was significant (χ^2 =333.74, df=4; P<0.01). COVID-19-related anxiety, HCW or FLW by occupation, and having diabetes mellitus were found to be significant correlates of psychological distress (Table IV). However, results of quantile regression coefficients at the 0.50 quantile (i.e. median) indicated that only COVID-19-related anxiety, and HCW or FLW by occupation were significant correlates of psychological distress (Table IV). In addition, similar multivariable analyses (i.e. generalized linear model and quantile regression) were conducted for the three DASS-21 sub-scale scores to determine significant correlates of depressive, anxiety and mental stress symptoms, respectively.

COVID-19-related anxiety, HCW or FLW by occupation, and educational attainment between

Study variable	Mean±SD/median (IQR) or frequency (%
Age (yr)	44.88±14.15/46.00 (32.00-55.00)
Gender	
Males	418 (57.4)
Female	310 (42.6)
Current living arrangement	
Alone	59 (8.1)
With family	621 (85.3)
With friend (s)	48 (6.6)
Occupation	
HCW/FLW	425 (58.4)
Others	303 (41.6)
History of close friend or family member requiring hospitalization from COVID-19	179 (24.6)
History of close friend or family member dying from COVID-19	93 (12.8)
History of laboratory-confirmed COVID-19	165 (22.7)
History of suspected COVID-19	90 (12.4)
Received second dose of COVID-19 vaccine	660 (90.7)
Any medical comorbidity	147 (20.2)
History of diabetes mellitus	86 (11.8)
CAS-7 score	11.59±3.31/11.00 (9.00-13.00)
DASS-21 score	30.81±10.38/30.00 (24.00-36.00)

Table II. Severity distribution of depression, anxiety, and stress symptoms in the study participants							
Depression		Anxiety		Stress			
Severity#	Frequency (%)	Severity#	Frequency (%)	Severity#	Frequency (%)		
Mild (10-13)	158 (21.7)	Mild (8-9)	70 (9.6)	Mild (15-18)	117 (16.1)		
Moderate (14-20)	304 (41.8)	Moderate (10-14)	34 (4.7)	Moderate (19-25)	61 (8.4)		
Severe (21-27)	44 (6.0)	Severe (15-19)	6 (0.8)	Severe (26-33)	44 (6.0)		
Extremely severe (28+)	8 (1.1)	Extremely severe (20+)	2 (0.3)	Extremely severe (34+)	6 (0.8)		
#The severity categorization was based on the cut-off values for the Depression Anxiety Stress sub-scale scores mentioned in the brackets							

10th and 12th standard (compared to graduation and above level) were found to be significant correlates of depressive symptoms. Similarly, COVID-19-related anxiety, HCW or FLW by occupation, educational attainment up to 12th standard (compared to graduation and above level), and having diabetes mellitus were found to be significant correlates of anxiety symptoms, whereas COVID-19-related anxiety, HCW or FLW by occupation, and having diabetes mellitus were found to be significant correlates of stress symptoms. The variables showing significant multivariable association with different sub-scale

scores of DASS-21 on generalized linear modelling were further tested by running quantile regression analyses at different quartiles. The effect of these variables was tested at different levels of depression, anxiety and stress through quantile regression analyses. Thus, COVID-19-related anxiety and HCW or FLW by occupation remained significant correlates of DASS-21 total as well sub-scale scores on both generalized linear and quantile regression analyses. The effect of COVID-19-related anxiety and working as HCW or FLW were the most consistent factors associated with increased psychological distress

Study variable	DASS-depression	DASS-anxiety	DASS-stress
Age ^a	-0.25 (<0.01)*	0.30 (<0.01)*	$0.08~(0.02)^{*}$
Gender ^b	62,043.00 (0.32)	50,743.00 (<0.01)*	61,316.00 (<0.21)
Current living arrangement ^o	14.60 (<0.01)*	15.64 (<0.01)*	1.48 (0.47)
Education level ^c	16.25 (<0.01)*	28.53 (<0.01)*	11.95 (<0.01)*
Occupation ^b	32,534.00 (<0.01)*	27,269.00 (<0.01)*	52,192.00 (<0.01)*
History of close friend or family member hospitalized with COVID-19 ^b	47,110.00 (0.40)	47,011.00 (0.35)	45,584.00 (0.14)
History of close friend or family member dying from COVID-19 ^b	26,067.00 (0.06)	27,024.50 (0.15)	26,623.00 (0.12)
History of laboratory confirmed COVID-19b	44,002.00 (0.30)	45,707.50 (0.73)	40,755.00 (0.01)*
History of suspected COVID-19 ^b	28,691.50 (0.99)	25,714.00 (0.08)	28,422.00 (0.87)
Received second dose of COVID-19 vaccine ^b	21,008.50 (0.38)	21,964.50 (0.75)	19,857.50 (0.11)
History of diabetes mellitus ^b	27,590.00 (0.99)	23,864.50 (0.02)*	22,893.00 (0.01)*
History of heart disease ^b	5511.00 (0.17)	4677.00 (0.01)*	6414.50 (0.72)
Other medical comorbidities ^b	No significant associations	No significant associations	No significant associations
CAS-7 scores ^a	0.19 (<0.01)*	0.36 (<0.01)*	0.44 (<0.01)*

Table IV. Comparison of psychological distress (i.e., Total DASS-21-score) correlates based on generalized linear model and quantile

B/estimate	95% CI (UB-LB)	Р
0.001	-0.001-0.003	0.495
0.077	0.068-0.086	< 0.001
0.066	0.003-0.130	0.041
0.308	0.256-0.360	< 0.001
2.293	2.124-2.461	< 0.001
0.021	-0.02-0.063	0.315
2.277	2.126-2.427	< 0.001
1.149	-0.219-2.517	0.999
5.362	4.064-6.660	< 0.001
-1.191	-4.434-2.051	0.471
	0.001 0.077 0.066 0.308 2.293 0.021 2.277 1.149 5.362	0.001 -0.001-0.003 0.077 0.068-0.086 0.066 0.003-0.130 0.308 0.256-0.360 2.293 2.124-2.461 0.021 -0.02-0.063 2.277 2.126-2.427 1.149 -0.219-2.517 5.362 4.064-6.660

Total DASS-21 score was the dependent variable and all other variables listed in the table (significant associations in bivariate analysis) were entered as independent variables. *B*, unstandardized coefficient; CI, confidence interval; UB, upper bound; LB, lower bound; DASS-21, Depression Anxiety Stress Scale-21; CAS-7, COVID-19-related Anxiety Scale-7; HCW, health-care worker; FLW, front-line worker; QR-50, quantile regression at the 0.50 quantile

and depressive symptoms. The association between COVID-19-related anxiety and psychological distress was also supported by the findings from studies conducted outside India, which reported a link between fear of COVID-19 and anxiety, and to a lesser extent with depression^{13,14}. Further, in line

with the available literature¹⁵, the HCWs and FLWs reported to experience higher levels of psychological distress during the COVID-19 pandemic in the present study. Possible reasons for this included a greater risk of getting infected due to a higher risk of exposure to COVID-19-positive individuals, perceived stigma and discrimination faced, increased work-related stress, inadequate sleep, burnout and moral injury associated with the death of patients due to lack of resources^{16,17}. Psychosocial support strategies aimed at improving the psychological well-being for this high-risk group need to be planned. Institutional implementation and involvement of HCWs/FLWs with providers of psychosocial support in the occupational setting itself by utilizing services of full-time or part-time mental health professionals, care managers, and peer support or mentoring networks to address the emotional needs (*e.g.* validation of negative emotions, normalization of mentally traumatic experiences) and strengthening of positive coping skills has been reported to improve psychological well-being^{18,19}.

Our study had certain limitations. The study participants were recruited from a single CVC at a tertiary care hospital by purposive sampling (prone to selection bias) and might not be generalizable for the entire population. The study was conducted in a convenience sample without any prior sample size calculation, and might not have been adequately powered to detect all the correlates of psychological distress. The cross-sectional study design limited causal assessment of factors associated with psychological distress. The lack of a comparative group consisting of non-vaccinated individuals also limits the interpretation of the present study findings. The study assessment was solely based only on self-report and was thus prone to social-desirability bias. Future studies with a more representative study sample and longitudinal study design should be conducted to test the validity of the findings of the present study.

In conclusion, the present study indicated that a significant number of people receiving the COVID-19 vaccine suffered from psychological distress expressed either as moderate-to-severe levels of depression, chronic mental stress and/or anxiety symptoms during the COVID-19 pandemic. People with higher COVID-19-related anxiety and those employed as HCWs and FLWs were at a greater risk of experiencing psychological distress.

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Conflicts of Interest: None.

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