Original Article

Development and Validation of A Situational Anxiety Scale Screening Assessment among Adults with Type 2 Diabetes During COVID-19 at A Tertiary Centre in Chennai, India

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Abstract

Aim: The aim of this study was to develop and validate the situational anxiety scale (SAS) during COVID-19 among adults with type 2 diabetes attending a tertiary diabetes center in Southern India. **Materials and Methods:** A total of 100 individuals aged from 18 to 65 years with type 2 diabetes attending a tertiary care diabetes center completed a structured SAS at two visits. The first visit (visit 1) survey was conducted in April 2021 and the second visit (visit 2) survey was conducted in March 2022. The SAS was administered to all 100 individuals. The State Trait Anxiety Inventory Scale (STAI-S) consisting of 20 questions was administered to the same 100 individuals in addition to the SAS during Visit 2. **Results:** The SAS showed good internal consistency for visit 1 (α = 0.855) and visit 2 (α = 0.795). Exploratory factor analysis showed four factors and explained 69% of variance. The four factors identified were as follows: (1) fear, (2) desire for COVID-free state, (3) lack of interest and energy, and (4) financial worries. A weak positive correlation was observed between SAS visit 2 and STAI-S, and it was statistically significant (r = 0.223; P = 0.026). **Conclusion:** The SAS is a valid and reliable tool for measuring situational anxiety during pandemics and post-COVID anxiety levels, which can help in the development of a holistic approach.

Keywords: Anxiety, coronavirus, hospital, India, situational anxiety scale, trait anxiety inventory, type 2 diabetes, validation

Introduction

The Coronavirus disease 2019 (COVID-19) is a global pandemic of unimaginable magnitude caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) risking millions of lives worldwide.[1] According to the World Health Organization (WHO), the disease is extremely contagious and spreads by droplets, direct contact with an infected individual, or contact of hands with contaminated environmental surfaces.[2] The COVID-19 infection spreads rapidly, and many countries in the world have been affected with it. WHO declared it a public health emergency of international concern on 30 January 2020 and emphasized the need of other countries to collaborate to prevent the rapid spread of COVID-19.[3]

India reported its first COVID-19 case on January 30, 2020, and the numbers began to rise by the second week of March 2020. A second wave of COVID-19 then resurfaced and ravaged in India; as a result, several instances of a deadly fungal disease called mucormycosis had been reported.[4] More than 28 million cases and 3.4 lakh fatalities were documented by May 2021. COVID-19 fatality rates and patients who had severe course of COVID-19 revealed that people with the number of chronic illnesses are at increased risk.[5] Further medical research has shown that individuals with diabetes are also at a higher risk due to their underlying disease and the frequent occurrence of comorbidities.[6]

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To deal this situation and to curb the community spread, governments all around the world devised novel measures such as social distancing, travel restrictions, self-quarantine, wearing a mask, and lockdown, and violation of which carried substantial fines.[7] Millions of people were forced to stay at homes and were confronted with new realities such as working from home, unemployment, online education, and lack of physical interaction with their friends and family members.[8] These sudden changes in people's life appear to have had far-reaching psychological consequences such as anxiety, fear, insomnia, depression, and emotional exhaustion.[9]

The fear created by COVID-19 pandemic and impact of lockdown measures have had a detrimental influence on the mental health and general well-being of entire societies, affecting communities at every level possible and is increasing rapidly.[10] The anxiety is compounded not only by rumors, together with flooding of information from the media and internet but also by economic instability. People are particularly worried that they or their family would be infected, fear of death, insecurities, hopelessness, and other mental health problems during this pandemic.[11]

Studies have reported that increased fear and anxiety due to COVID-19 have resulted in poor psychological well-being,[12] increase in suicidal tendencies,[13] and aggravation of pre-existing mental health conditions.[14] Additionally, it has also severely affected the family relationships, social dynamics,[15] domestic violence instances,[16] and alcohol abuse.[17] According to studies people who are at risk owing to chronic illness report higher levels of worries and fears due to COVID-19 and show overall an increased psychological burden.[18]

Fear and anxiety could weaken the immune system and make people more susceptible to respiratory infection and also decrease the quality of life with substantial impact on their work and family life.[19] According to experiences from similar outbreaks and pandemics, patients may experience serious anxiety such as fear of death and feelings of loneliness and anger among quarantined people. A study showed that individuals with comorbid conditions have higher level of anxiety in the face of COVID-19 pandemics compared to those with any comorbidities.[20] Anxiety in patients with type 2 diabetes and other comorbidities, if left undiagnosed, could exacerbate the underlying disorder.

At this instance, it is important to diagnose anxiety and related factors. Despite COVID-19, epidemic diseases will continue to aggravate anxiety and fear. The aim of the study was to address this gap by creating an easy-to-use tool that could be used in any pandemic as well as during or after COVID-19 to measure anxiety levels for comparison.

Materials and Methods

Study design

This is a cross sectional design which has looked at the development of anxiety tool.

Setting

Participants aged between 18 and 65 years with type 2 diabetes attending a tertiary care center for routine check-up in Chennai, India were invited to participate in the study. The study process was explained to the participants in detail and a written informed consent was obtained from them after making them sit in a comfortable position. A self-reported situational anxiety scale (SAS) developed by the psychologists was administered to the participants. The first visit (visit 1) survey was conducted in April 2021 during second wave of COVID-19 and the second visit (visit 2) survey was conducted in March 2022 during the third wave of COVID-19. For assessing validity, the baseline was collected in the month of April 2020 (visit 1) and the repeated data were collected after 11 months (visit 2) by a trained research staff. State Trait Anxiety Inventory Scale (STAI-S) consisting of 20 questions, which is a part of STAI, was administered along with SAS during Visit-2. The study was conducted in accordance with the Helsinki Declaration and the ethics committee approval was received from the Ethics Committee of the Institute.

Participants

Sociodemographic information such as the age, gender, marital status, educational status, and occupational status of the study participants was collected at baseline for the purpose of the study.

Anthropometric measures such as height and weight of the participants were acquired using standard techniques. Body mass index (BMI) of the participants was determined using weight (kg)/height (cm) squared formula. Blood pressure was measured in a sitting position using electronic OMRON equipment.

Study size

A sample size of 100 participants were randomly selected using computer generated system from a tertiary care center in Chennai, India.

Materials

The items for SAS were pooled from the COVID-19 anxiety scale as well as additional items were framed keeping in view the experiences of people during pandemic. The questionnaire was aimed at getting a quick assessment of presence of anxiety. The item pooling resulted in 12-item scale indicating specific features of anxiety associated with COVID-19 [shown in Table 1]. The SAS focused on the following—fear, thoughts, sleep, behavior and

Table 1: The situational anxiety scale (SAS)

No	Questions	Never	Rarely	Often	Always
1.	Fear of being infected with COVID-19				
2.	Fear of stepping out from home				
3.	I feel tensed about COVID-19				
4.	I am unable to sleep when thinking about COVID-19				
5.	I feel overcautious				
6.	I worry about finance				
7.	I feel things may go bad				
8.	I lack interest in doing things due to COVID-19				
9.	News about COVID-19 makes me sick				
10.	I feel energetic throughout the day				
11.	I felt as if COVID-19 has not happened				
12.	I stayed away from reminders about COVID-19				

financial worries that participants would have experienced in association with COVID-19 pandemics. The frequency of each item was rated on a 4-point Likert scale which includes never (1), rarely (2), often (3), and always (4). One of the positively stated items (item no: 10) was computed by reverse coding [1 = 4], [2 = 3], [3 = 2], and [4 = 1]. The overall assessment score was obtained by summing up of all the scores across 12 items. The total situational anxiety scores ranged from 0 to 36 with the higher scores reflective of increased COVID-19 related anxieties.

The STAI is a commonly used tool in clinical setting to diagnose anxiety consisting 40 self-reporting questions on a 4-point Likert scale. There are two subscales with in this scale. First, the State Anxiety Scale (S-Anxiety) evaluates the current state of anxiety, asking how respondents feel "right now," using items that measure subjective feelings of apprehension, tension, nervousness, worry, and activation/arousal of the autonomic nervous system. The Trait Anxiety Scale (T-Anxiety) evaluates relatively stable aspects of "anxiety proneness," including general states of calmness, confidence, and security. In this study, the State Anxiety Scale (S-Anxiety) was used to assess the concurrent validity of the SAS. A total of 100 responses were collected at two points for the validation of the study.

Statistical methods

Statistically analysis was done using IBM SPSS software (Version 25.0, Chicago, IL). For continuous variables, mean and standard deviation and for categorical variables, percentages and frequency were used. To measure the internal consistency of SAS, Cronbach's α test was performed. To examine the construct of the SAS, exploratory factor analysis was performed. The Kaiser–Meyer–Olkin measure and Bartlett's test of sphericity was examined to check the sampling adequacy. Eigen values, factor loadings and proportion of variance explained were examined to explore factor structure. Pearson correlation test was used to assess the concurrent validity of the SAS. A P value of < 0.05 was considered statistically significant and otherwise non-significant.

Table 2: Baseline characteristics of the participants (n = 100)

Variables	Mean (SD)
Age (years)	57 (9.0)
Men (%)	53%
Weight (kg)	67.4 (12.6)
Body mass index (kg/m^2)	26.3 (4.3)
Systolic blood pressure (mmHg)	130 (12)
Diastolic blood pressure (mmHg)	79 (8)
Socio economic status (%)	
Low income	44
Middle income	36
High income	20
Marital status (%)	100
Educational status (%)	
Below SSC	37
Only SSC	32
Graduate	24
Postgraduate	5
Professional	2

SSC: secondary school certificate

Results

A total of 100 responses were collected. As shown in Table 2, the mean (SD) age of participants was 57 (9.0) years; 53% were men, 44% were from low-income group; 31% participants had more than a high school degree, and all the participants were married. The mean (SD) BMI of participants was 26.3 (4.3) kg/m^2. The mean systolic blood pressure of the participants (12) was 130 mmHg. The mean diastolic blood pressure of the participants (8) was 79 mmHg.

Reliability

Cronbach's α coefficient calculated for the evaluation of the internal consistency (homogeneity) of the SAS questionnaire was determined as 0.853 which indicates high reliability of the scale. During visit 2; the alpha co-efficient for the SAS was 0.795 and the internal

Table 3: Reliability of the SAS and STAI tool

Scale	Cronbach's α	Cronbach's α based on standardized items	No of items
SAS visit 1	0.853	0.855	12
SAS visit 2	0.795	0.837	12
STAI	0.937	0.938	20

Table 4: Kaiser-Meyer-Olkin and Barlett's—sphericity test of SAS

Kaiser-Meyer-Olkin coefficient	0.827
Chi square	505.317
Df	66
P value	<0.001

consistency of Trait Anxiety Inventory scale was 0.937 which indicates high reliability of the scale [Table 3].

Validity of the scale

Before performing factor analysis, the suitability of the sample to factor analysis was evaluated by Kaiser-Meyer-Olkin (KMO) sample adequacy measure. KMO value was found to be 0.827 which indicates high strength in the relationship among items. The Bartlett's test of sphericity was significant (χ = 505.317, df = 66 and P < 0.001) [Table 4].

To identify number of extractable factors, principal component extraction with direct oblique rotation was performed. The principal component analysis resulted in four factors [as shown in Table 5] and these factors accounted for substantial amount of variance, that is, 69%. Factor 1 accounted for most of the variance (41.4%) followed by factor 2 (10.3%), factor 3 (9.0%), and factor 4 (8.5%). When the items were evaluated according to their content, it was observed that factor 1 indicated fear which is an important driver of anxiety; factor 2 indicated desire for a COVID-free state; factor 3 indicated a lack of interest in doing things and feeling less energetic; and factor 4 indicated financial worries. Factor 1 was including 7 items (1, 2, 3, 4, 5, 6, 7); factor 2 contains 2 items (8, 9); factor 3 has 2 items (10, 11) and factor 4 has 2 items (9, 12). Item 9 is loaded on factor 2 and factor 4. It has higher loading on factor 2 than 4 and also more meaningfully associated with the other item in factor 2. The item 12 was also a valid item, but it is indicative of anxiety related to financial issues and thus retained as a factor.

Pearson correlation was used to examine the concurrent validity between SAS and STAI. Table 6 illustrates that a weak positive correlation was observed between SAS visit 1 and SAS visit 2 scores and it is statistically insignificant (r = 0.075; P = 0.458). The SAS shows a weak positive correlation with the Trait Anxiety Scale and is statistically significant (r = 0.223; P = 0.026).

Table 5: Factor loadings in SAS

Item	Component			
	Factor 1	Factor 2	Factor 3	Factor 4
Fear of being infected with COVID-19	0.911			
Fear of stepping out from home	0.883			
I feel tensed about COVID-19	0.836			
I am unable to sleep when thinking about COVID-19	0.718			
I feel things may go bad	0.683			
I feel overcautious	0.672			
News about COVID-19 makes me sick	0.657			
I stayed away from reminders about COVID-19		0.857		
I felt as if COVID-19 has not happened		0.621		0.529
I feel energetic throughout the day			0.856	
I lack interest in doing things due to COVID-19			0.741	
I worry about finance				0.907

Table 6: Correlation of the situational anxiety scale (SAS) and state trait anxiety score

		SAS visit 1	SAS visit 2	State trait anxiety score
SAS visit 1	Pearson correlation	1	0.075	–
	Sig. (2-tailed)		0.458	
SAS visit 2	Pearson correlation	0.075	1	0.223
	Sig. (2-tailed)	0.458		0.026*
State trait anxiety score	Pearson correlation	–	0.223	1
	Sig. (2-tailed)		0.026*	

* Correlation is significant at the 0.05 level (2-tailed)

Discussion

The primary objective of the study was to develop and validate the SAS to help health professionals to measure situational anxiety related to COVID-19 and also anxiety related to any other out-breaks. We found that the SAS is a valid and reliable scale for measuring the anxiety associated with COVID-19 in a hospital setting. We found the Cronbach's α obtained from SAS was 0.853. Thus, the SAS is highly reliable as its alpha value lies between 0.7 and 0.9. In addition, exploratory factor analysis revealed a four-factor solution for the SAS.

A study in Uttar Pradesh, India showed that 53% of the Indians perceive some form of psychological stress; 47% expressed fear and 3.3% expressed anxiety due to COVID-19.[21] Many individuals adapt to the circumstances and take preventive measures recommended by public health professionals, but others face challenges to adjust which results in fear and anxiety.[22] Between March and May 2020, one study reported 72 suicidal cases in India, with

fear of COVID-19 infection being the most common reason.[23] It is vital to identify people with fear of infection and assist them by promoting adaptive coping techniques and counselling and this is possible only by using a tool which is more appropriate to measure the anxiety levels arising as a result of COVID-19 or any pandemic situations.

The Coronavirus Anxiety Scale developed by Lee in the year 2020, consists of 5 items and reported adequate reliability with Cronbach's α coefficient value 0.92 and 0.93 among a US population[24,25] and 0.80 among a Turkish population.[26] Singh *et al.*[27] performed validation of CAS scale developed by Lee among Indian population and showed a Cronbach's α coefficient of 0.822 which is almost similar to present study Chandu *et al*.[28] developed a 7-item COVID-19 Anxiety Scale to measure COVID-19 related anxiety among Indian population and its reliability was reported to be 0.736 which is slightly lower than the SAS ($\alpha = 0.853$).

One of the limitations of the study is small sample size. Secondly, it is a clinic-based study and thus it is not generalizable to the whole of India. Thirdly, the outcomes were self-reported which carries source and recall bias. Another limitation includes loadings of only two items on factors 2 and 3 and one on factor 4. Although a minimum of three items for a factor is suggested, it is common in literature for a subscale to have two items.[29,30] Further studies are needed to replicate the results in the current study using larger sample and other assessment techniques like discriminate validity. However, based on the results from this study we suggest that the SAS is a valid and reliable tool that can be used to measure COVID-19-related anxiety among the Indian population.

In conclusion, the SAS is effective in screening anxiety associated with outbreaks of COVID-19 and to make comparison with post-COVID anxiety levels. The scale could be used to measure anxiety levels associated with any infectious outbreaks. Incorporating this tool in clinical settings during pandemics would be beneficial for the patients and would aid in reduction and management of anxiety burden in the population.

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Conflicts of interest

There are no conflicts of interest.

References

1. Epidemiology Working Group for NCIP Epidemic Response, Chinese Center for Disease Control and Prevention. The epidemiological characteristics of an outbreak of 2019 novel coronavirus diseases (COVID-19) in China. Zhonghua Liu Xing Bing Xue Za Zhi 2020;41:145-51.
2. World Health Organization. Modes of transmission of virus causing COVID-19: Implications for IPC precaution recommendations: scientific brief. World Health Organization; 2020. https://apps.who.int/iris/handle/10665/331601. [Last accessed on 27 Mar 2020].
3. Shrivastava SR, Shrivastava PS. 2019-nCoV outbreak declared as public health emergency of international concern: What next? Int J Prev Med 2020;11:65.
4. Choudhary NK, Jain AK, Soni R, Gahlot AK. Mucormycosis: A deadly black fungus infection among COVID-19 patients in India. Clin Epidemiol Glob Health 2021;12:100900.
5. Yang J, Zheng Y, Gou X, Pu K, Chen Z, Guo Q, *et al*. Prevalence of comorbidities and its effects in patients infected with SARS-CoV-2: A systematic review and meta-analysis. Int J Infect Dis 2020;94:91-5.
6. Cariou B, Hadjadj S, Wargny M, Pichelin M, Al-Salameh A, Allix I, *et al*. Phenotypic characteristics and prognosis of inpatients with COVID-19 and diabetes: The CORONADO study. Diabetologia 2020;63:1500-15.
7. Anderson RM, Heesterbeek H, Klinkenberg D, Hollingsworth TD. How will country-based mitigation measures influence the course of the COVID-19 epidemic? Lancet Lond Engl 2020;395:931-4.
8. Huang C, Wang Y, Li X, Ren L, Zhao J, Hu Y, *et al*. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. Lancet Lond Engl 2020;395:497-506.
9. Brooks SK, Webster RK, Smith LE, Woodland L, Wessely S, Greenberg N, *et al*. The psychological impact of quarantine and how to reduce it: Rapid review of the evidence. Lancet 2020;395:912-20.
10. Ahorsu DK, Lin CY, Imani V, Saffari M, Griffiths MD, Pakpour AH. The fear of COVID-19 scale: Development and initial validation. Int J Ment Health Addict 2022;20:1537-45.
11. Rana W, Mukhtar S, Mukhtar S. Mental health of medical workers in Pakistan during the pandemic COVID-19 outbreak. Asian J Psychiatry 2020;51:102080.
12. Saladino V, Algeri D, Auriemma V. The psychological and social impact of covid-19: New perspectives of well-being. Front Psychol 2020;11:577684.
13. Sher L. Psychiatric disorders and suicide in the COVID-19 era. QJM 2020;113:527-8.
14. Asmundson GJG, Paluszek MM, Landry CA, Rachor GS, McKay D, Taylor S. Do pre-existing anxiety-related and mood disorders differentially impact COVID-19 stress responses and coping? J Anxiety Disord 2020;74:102271.
15. Pietromonaco PR, Overall NC. Applying relationship science to evaluate how the COVID-19 pandemic may impact couples' relationships. Am Psychol 2021;76:438-50.
16. Buttell F, Ferreira RJ. The hidden disaster of COVID-19: Intimate partner violence. Psychol Trauma Theory Res Pract Policy 2020;12:S197-8.
17. Clay JM, Parker MO. Alcohol use and misuse during the COVID-19 pandemic: A potential public health crisis? Lancet Public Health 2020;5:e259.
18. Bäuerle A, Teufel M, Musche V, Weismüller B, Kohler H, Hetkamp M, *et al*. Increased generalized anxiety, depression and distress during the COVID-19 pandemic: A cross-sectional study in Germany. J Public Health Oxf Engl 2020;42:672-8.
19. Barrera TL, Norton PJ. Quality of life impairment in generalized anxiety disorder, social phobia, and panic disorder. J Anxiety Disord 2009;23:1086-90.
20. Ozamiz-Etxebarria N, Dosil-Santamaria M, Picaza-Gorrochategui M, Idoiaga-Mondragon N. Stress, anxiety, and depression levels in the initial stage of the COVID-19 outbreak in a population sample in the northern Spain. Cad Saude Publica 2020;36:e00054020.
21. Srivastava A, Bala R, Srivastava A, Mishra A, Shamim R, Sinha P. Anxiety, obsession and fear from coronavirus in Indian population: A web-based study using COVID-19 specific scales. Int J Commun Med Public Health 2020;7:4570-7.
22. Dsouza DD, Quadros S, Hyderabadwala ZJ, Mamun MA. Aggregated COVID-19 suicide incidences in India: Fear of COVID-19 infection is the prominent causative factor. Psychiatry Res 2020;290:113145.

23. Patel A, Jernigan DB, 2019-nCoV CDC Response Team. Initial public health response and interim clinical guidance for the 2019 novel coronavirus outbreak—United States, December 31, 2019–February 4, 2020. MMWR Morb Mortal Wkly Rep 2020;69:140-6.
24. Lee SA. Replication analysis of the Coronavirus Anxiety Scale. Dusunen Adam J Psychiatry Neurol Sci 2020;33:203-205.
25. Lee SA. Coronavirus Anxiety Scale: A brief mental health screener for COVID-19 related anxiety. Death Stud 2020;44:393-401.
26. Evren C, Evren B, Dalbudak E, Topcu M, Kutlu N. Measuring anxiety related to COVID-19: A Turkish validation study of the Coronavirus Anxiety Scale. Death Stud 2022;46:1052-8.
27. Singh KD. Coronavirus anxiety scale: A validation study in an Indian population. Med J Dr Patil Vidyapeeth 2021;14:303.
28. Chandu VC, Pachava S, Vadapalli V, Marella Y. Development and initial validation of the COVID-19 anxiety scale. Indian J Public Health 2020;64(Supplement):201S201-4.
29. Gosling SD, Rentfrow PJ, Swann WB. A very brief measure of the big-five personality domains. J Res Personal 2003;37: 504-28.
30. Jansson BS, Nyamathi A, Duan L, Kaplan C, Heidemann G, Ananias D. Validation of the patient advocacy engagement scale for health professionals. Res Nurs Health 2015;38:162-72.