

Pandemic anxiety stress scale for pregnant women(PASSP): Development and validation

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ABSTRACT

Introduction

Coronavirus disease (COVID-19) is a new pandemic caused by a newly discovered coronavirus. This pandemic has caused increase in anxiety among people globally and more the pregnant women. Elevated levels of anxiety and stress may adversely affect the outcome.

Aim & Objective: This study aimed at developing and validating a tool to assess the stress and anxiety due to pandemic which helps the health care professionals to identify the probable cases of anxiety associated with the coronavirus and can take adequate measures to improve the emotional well-being of the antenatal women.

Methods & Material: A cross-sectional survey was carried out among the pregnant women in Kerala using a 29-item tool through google forms during the month of June. **Statistical Analysis:** Item analysis, Exploratory factor analysis and confirmatory factor analysis were done to evaluate scale dimensionality, factor loadings, and factor structure using the R Software version 4.0.2.

Results: Factor analysis resulted in a 15-item short tool, Pandemic anxiety stress scale for pregnant women (PASSP) with the reliably index of Cronbach's alpha of 0.93. Exploratory factor analysis extracted two factors. Confirmatory factor analysis confirmed the factor structure of the PASSP with Goodness of fit indices. Two factor model structure has good fit indices with GFI>0.90, DFI and TLI>0.95 and SRMR =0.04.

Discussion: This study developed a new validated instrument PASSP for assessing the anxiety and stress due to a pandemic among pregnant women in Kerala.

Key words: COVID19–anxiety–pandemic–pregnancy–tool validation–factor analysis

1 INTRODUCTION

Coronavirus (COVID-19) is a new pandemic that is spreading widely throughout the world. The first SARS-CoV-2 positive case in India was reported in the state of Kerala on January 30th, 2020.¹ As of 23rd November 2020, the Ministry of Health and family Welfare have reported a total of 4,38,667 active cases, 86,049,55 cumulative discharged cases and 1,34,218 cumulative deaths in the country, where as a total of 64,292 active cases, 5,00,089 cumulative recoveries and 2071 total deaths reported in Kerala.² The Covid-19 pandemic has caused increase in anxiety among people globally and more the pregnant women.³ In a pandemic situation women are most concerned firstly about older relatives,

then their children, followed by their unborn child.⁴ Many pregnant women may avoid seeing their gynaecologist due to concerns that they may be exposed to the corona virus in the hospital environment or on the way to the hospital. Many pregnant women have planned their delivery before the pandemic, but are currently worried about how their families will be able to support, due to travel restrictions, and risk of getting infected during travel. Perceptions regarding the susceptibility and severity of infection makes the vulnerable anxious and lead to change in behaviours.^{5,6} The restrictions related to social distancing have put a strain on individuals, families, societies and countries.⁷ Elevated levels of anxiety and depression during pregnancy contribute adverse obstetric, foetal and neonatal outcome.⁸ Pandemic situations may elevate the anxiety and stress during pregnancy. In research settings, antenatal anxiety has been mea-

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sured with a heterogeneity of self-report scales in pregnant populations.⁹ An online survey conducted in India revealed one third of respondents had significant psychological impact, higher impact was predicted with younger age and female gender.¹⁰ Screening for antenatal anxiety using scales developed for normal scenarios problematic for various reasons. These scales may fail to assess the added stress and anxiety developed due to a pandemic and its control measures like lockdown, social distancing, fear of transmitting the corona virus etc. The study aims to develop and validate a tool to assess the stress and anxiety among pregnant women due to pandemic. The tool may help health care professionals and researchers to identify the probable cases of anxiety associated with the corona virus and can take adequate measures to improve the emotional well-being of the antenatal women.

2 METHOD

A cross-sectional survey was conducted among antenatal women in Kerala during June, 2020. A 34-item questionnaire was finalised for the survey and the google form link was shared to antenatal women. Period of survey was restricted to two weeks considering the rapidly changing pandemic situation. Two twenty antenatal women participated in the survey.

1. Scale development

A total of 34 items were developed based on the anxiety and stress during the COVID-19 pandemic. The items were framed in such a way that, during the past month how often they worried about acquiring corona viruses, problems faced because of lockdown, social distancing, transportation, hospital visits, worry about their family and job. Response options were “never”, “rarely”, “sometimes”, “often”, and “always” and scored as 0, 1, 2, 3 and 4 respectively. Our goal was to determine the number of items needed to achieve good reliability and validity. Two experts assessed the face validity of the tool. Pre testing of the tool was done on 25 samples selected from the Obstetrics and Gynaecology department of a tertiary care teaching hospital in South Kerala. Item analysis resulted in deletion of five questions and three questions were reworded according to the suggestions of the participants to get more clarity, which resulted in a 29-item scale with reliability coefficient of Cronbach’s alpha (α) as 0.84.

2. Data collection procedure

The self-reported questionnaire was both in English and Malayalam, the regional language of Kerala. Questionnaire was created in google forms, with a consent form appended to it. The link of the questionnaire was sent through emails, WhatsApp and SMS to the contacts of the investigators. The participants were encouraged to roll out the survey to as many antenatal women as possible. By clicking the link, the participants were directed to the information about the study and informed consent. If they agreed to participate, they have to go through a set of questions sequentially followed by the socio-demographic variables such as age, dis-

trict, education, occupation, area of residence, type of family etc. The tool consists of items to assess the anxiety and stress due to corona virus spread during the past month.

3. Sample size

According to Kline¹¹, a sample of 200 or more is “large”, recommended for factor analysis. Exploratory factor analysis was done on 220 samples and confirmatory factor analysis on 216 samples.

4. Analysis approach

Statistical analysis was performed using R software version 4.0.2. Data were analysed using descriptive statistics, item analysis, exploratory factor analysis (EFA) and confirmatory factor analysis (CFA). The scale scores were analysed using mean, standard deviation (SD), response values frequency. Reliability was established using tests of internal consistency. Cronbach’s α statistic was used in the assessment of internal consistency of the instrument. An α coefficient score >0.7 was considered to be satisfactory.¹² EFA was employed to data reduction and to identify the underlying factors.¹³ CFA was carried out to test the relevance of the scale constructed through EFA. That is the factor structure of the model derived through EFA is confirmed with the goodness of fit indices of CFA. Maximum likelihood estimation was used to assess the model fit. According to the recommendations of Brown, chi-square value, the standardized root mean square residual (SRMR), and the root mean square error of approximation (RMSEA), comparative fit index (CFI), goodness of fit index (GFI), Adjusted Goodness of Fit Index (AGFI), normed fit index (NFI), and Tucker-Lewis Index (TLI) were computed to examine the model fit.¹⁴ SRMR values less than 0.08, RMSEA value less than 0.06 and GFI, and NFI values close to 0.90 or higher indicate a good fit, CFI/TLI values more than 0.95 indicates good fit. Convergent validity was assessed using the indices construct reliability (CR) and average variance extract (AVE) Model diagnostics were done using standardised residuals and modification indices (MI). R packages such as Psych, GProtation, lavaan and SemPlot were used for analysis.

3 RESULTS

In the first stage a total of 220 responses were analysed. The mean age of the respondents were 26.19 years (SD =3.78 ; range = 18–35). Among the participants 29.8% had professional qualification, 19.5% were postgraduates, 35.9% were graduates, 15% were pul2, 2.3% were high school education and 0.5% had primary school education. Most of the respondents were from Panchayath area (65.9%) followed by 20% from municipality and 14.1% from corporation area. About half of the participants (50.4%) belong to nuclear families and 35% were employees.

1. Item analysis

Item analysis was done. Means for items ranged from to 0.97 to 3.1 (Standard deviation ranged from 0.8 to 1.2). The scores for all items did not exceed 2.5 SD from the mean, which indicate all items were adequate. Two items with item-total correlations less than 0.30 were excluded which

resulted in 27 item tool. Item-total correlation ranged from 0.31 to 0.68. Reliability statistic was 0.93. On the basis of item analysis 27 items were included for next step analysis.

2.Exploratory factor analysis

To identify multivariate outliers Mahalanobi’s distance values were calculated, which is a very conservative probability estimate for being identify a case as an outlier.¹⁵ A total of four samples were identified as multivariate outliers based on cut-off value of $\chi^2_{(27)} = 55.47$ with $p=0.001$. These participants were excluded from further analysis, leaving a total sample size of $n=216$. Additivity assumption was checked using bivariate correlation between all items. All correlations below 0.90, indicated that assumption was satisfied. Visual inspection of Q-Q plots, histogram of standardized residuals, and scatter plot of standardized fitted values predicting standardized residuals suggested that multivariate linearity, normality, and homoscedasticity assumptions were met. Bartlett’s test of sphericity indicated correlation adequacy, $\chi^2_{(351)} = 3102.6$, $p<0.001$. Kaiser-Meyer-Olkin (KMO) value indicated sampling adequacy, Measure of sampling adequacy (MSA) =0.92. A parallel analysis suggested two factors. Scree plot in Figure 1 confirmed the findings of retaining 2 factors. Maximum likelihood estimation was used with direct oblimin rotation because of expected factor correlation. Moreover, when EFA is used as a precursor to CFA oblique solutions are more likely to generalize to CFA than orthogonal solutions.¹⁴ After testing for 27 questions using repeated factor analysis using oblimin rotation, 15 items were retained. Items with factor loadings below 0.45 and cross loading of items with values ≥ 0.30 were-deleted. Factor 1 consists of 10 items related to anxiety and factor 2 composed of 5 items on stress. Factor 1 is named as anxiety and Factor 2 as stress. The 15-itemscale with factor loading are presented in Table 1.

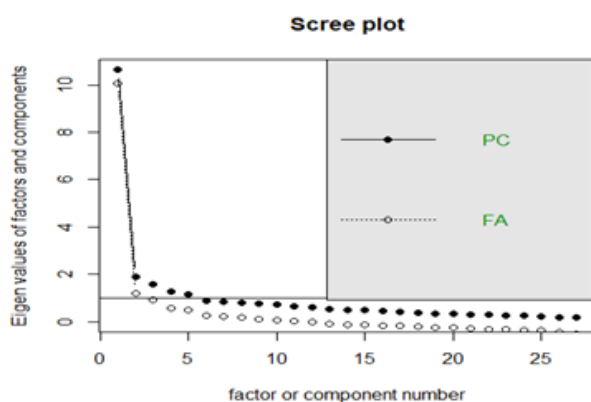


Figure 1. Scree Plot

This two-factor model achieved simple structure with each item loading on one and only one factor. The overall scale reliability for the items was very good, with Cronbach’s alpha of 0.93. Cronbach’s alpha for factor1 is 0.91 and factor2 is 0.82. This model has good fit with CFI=0.92, TLI=0.90, RMSEA=0.09; 90% CI: 0.07-0.10.

3.Confirmatory Factor Analysis

A CFA was run to test whether or not the two constructs identified through the previous EFA together constitute a pandemic anxiety-stress scale. All assumptions for CFA were verified. Modification indices (MI) and expected parameter change (EPC) were examined in order to help identify focal areas of misfit in the CFA solution. The results of CFA are given in Table 2. Table 2 illustrates that fit indices improved when the two-factor correlated model is compared with the other two models. To inspect the convergent validity, Average variance extracted (AVE) values were computed. AVE for factor 1 is 0.51 and factor 2 is 0.53 which indicates convergent validity. Construct reliability (CR) values for factor 1 is 0.91 and for factor 2 is 0.82 which assures construct reliability.

4.Anxiety-stress using PASSP

Total score was computed by adding all the items. Individual total scores on the PASSP can range from 0 to 60 with higher scores indicating higher perceived anxiety-stress. Scores ranging from 0-14 were considered as normal, 15-29 as mild, 30-44 as moderate and from 45-60 were considered severe perceived anxiety- stress.

4 DISCUSSION

The purpose of this study was to develop and validate a brief mental health screener that helps health care professionals and researchers to identify probable cases of dysfunctional anxiety associated with the pandemic. There are several standard tools available to assess the anxiety and stress, but not pertained to a pandemic. So, through this study we developed a new tool (PASSP) for assessing the anxiety due to COVID-19 pandemic among pregnant women. A 34-item tool was developed and a pilot study was done to check the reliability of the tool. During item analysis phase this reduced to a 29-item tool with very good reliability index of 0.84. EFA reduced the tool into a short form with two subscales. The full measure attained an α value of 0.93 and α values greater than 0.8 were obtained for two subscales. The reliability statistics are higher assuring high internal consistency. A study conducted in Wuhan and Chongqing in China used Self-Rating Anxiety Scale (SAS) for assessing the anxiety, reported the reliability coefficient of α value as 0.78, reported mild anxiety level for 13.87% and moderate/severe anxiety for 3.29%.¹⁶ But in the present study 5.5% had severe, 70.5% had moderate and 38.6% had mild anxiety. A preliminary study conducted in Turkey to assess the effects of the COVID-19 pandemic on anxiety and depressive symptoms in pregnant women used the Edinburgh Postpartum Depression Scale (EPDS), Beck Depression Inventory (BDI) and Beck Anxiety Inventory (BAI).¹⁷ They had translated the tool into their regional language Turkish and validated. But the validation indices were not reported and hence couldn’t compare. BAI findings implied that they exhibited higher levels of anxiety than usual. Another study conducted among Jewish and Arab pregnant women in Israel on anxiety and distress used a eight item scale on anxiety and Mental Health Inventory- Short Form(MHI)¹⁸. The

Table 1. Developed PASSP: Factor loadings of Exploratory Factor Analysis

Items	Factor1 (Anxiety)	Factor2 (Stress)
1. In the last month, how often have you worried about getting infected with coronavirus?	0.65	0.06
2. In the past month, how often have you been worried that corona virus will be infected by hospital visits?	0.68	0.09
3. In the last month, how often have you been upset because of the recent changes happened unexpectedly?	0.52	0.28
4. In the last month, how often have you felt that you were unable to control the important things in your life?	0.09	0.61
5. In the last month, how often have you felt nervous and stressed?	0.07	0.81
6. In the last month, how often have you felt that you could not tackle all the things that you had to do?	-0.01	0.69
7. In the last month, how often have you been angered because of things that are outside your control?	0.07	0.61
8. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	-0.06	0.81
9. In the past month, how often have you worried about getting medical supplements?	0.59	0.16
10. In the past month, how many times have you worried about any medical illness as associated with pregnancy	0.52	0.23
11. In the past month, how many times have you worried about your unborn baby being affected by COVID 19?	0.87	-0.05
12. How often have you worried that the new born will have to go through this epidemic?	0.85	-0.17
13. In the past month, how often have you worried about your family and other children if any?	0.61	0.08
14. In the last month, how often had you been unable to sleep comfortably due to thoughts related to this pandemic?	0.47	0.22
15. In the last month, how often have you worried of getting this pandemic when a stranger come close to you?	0.71	0.04
Sum of squares of loadings	4.70	3.24
Proportion of Variance	0.31	0.22
Cumulative Variance	0.31	0.53
Proportion Explained	0.59	0.41
Cumulative Proportion	0.59	1.00

Table 2. Goodness of fit measures of CFA

Goodness of fit indices	Model		
	Single Factor	Two factors	Two factors correlated
AIC	8591.82	8458.00	8370.65
BIC	8693.083	8562.64	8488.77
χ^2/df	3.79	2.82	1.93
SRMR	0.06	0.05	0.04
RMSEA	0.11	0.09	0.06
GFI	0.80	0.86	0.92
AGFI	0.73	0.82	0.88
NFI	0.81	0.86	0.91
CFI	0.85	0.90	0.96
TLI	0.83	0.88	0.95

Table 3. Anxiety-stress level

PASSP score category	Frequency (%)
Normal	53(24.1)
Mild	85(38.6)
Moderate	70(31.8)
Severe	12(5.5)

The mean anxiety-stress score is 24.43 with standard deviation of 11.99.

Cronbach's alpha of MHI was 0.80, which is less than that of PASSP. The anxiety tool had mean score of 3.03 with a standard deviation of 0.86, in which the score for an item ranges from 1 to 5, indicates the presence of anxiety. A study conducted in China among pregnant women in the third trimester during COVID-19 epidemic used Self-Rating Anxiety Scale (SAS) to study the anxiety level.¹⁹ This study reported 14.3% had mild, 1.6% had moderate anxiety level and 0.3% had high level of anxiety, which is less than that reported in the present study. In this study conducted in China, they had created a structural equation model (SEM) by taking anxiety as the dependent variable, social support as the independent variable and risk perception as the mediating variable. The model fitting index showed that χ^2/df was 1.228, RMSEA was 0.027, CFI was 0.994, NFI was 0.969, NIFI was 0.994, TLI was 0.990 and GFI was 0.986. These indices were all within the acceptable range, indicating that the model had a good fit. In our study we had performed a CFA, a subclass of SEM to confirm the results of EFA and obtained the fit indices as $\chi^2/df = 1.93$, RMSEA=0.07, CFI=0.96, NFI=0.91, TLI=0.95 and GFI=0.92. One more study conducted in China used EPDS to assess the perinatal depressive and anxiety symptoms of pregnant women.²⁰

A study conducted among Iranian pregnant women reported extremely severe anxiety among 7.8%, severe anxiety among 6.3%, moderate anxiety among 12.2% and mild anxiety among 17.6% respectively. Extremely severe stress among 1.5%, severe stress among 7.8%, moderate stress among 15.6%, mild stress among 7.8% respectively. About 67.3% are categorised as normal stress and 56.1% with normal anxiety level.²¹ But in this present study only 24.1% were under normal category and majority (70.4%) were in mild/moderate category. A nation wide survey conducted by Moyer et al concluded that women were anxious about being pregnant during COVID 19 with mean score of 6.5 in a scale of 1 to 10 with 95% confidence interval: 6.5-6.6.²² A study conducted in southern Turkey reported that, the perceived stress levels of pregnant women who were very much affected by the COVID-19 pandemic were higher than those who were affected at medium-low levels 29.32 ± 5.13 Vs 27.81 ± 5.52 .²³

The mean score is almost consistent with that of the present study, where the mean \pm SD score is 24.43 ± 11.99 .

A study conducted in Italy used the Spielberger State-Trait Anxiety Inventory (STAI) and visual analogue scale (VAS) for assessing the anxiety, 53% rated severe psychological impact, almost half of the women (46%) reported high anxiety regarding the vertical transmission of the disease, assessed as VAS for anxiety.²³ The Generalised Anxiety Score 7 (GAD-7) was used to screen for maternal anxiety in a study conducted in UK, reported the median GAD-7 score of 3 (mild) throughout the 11-week period.²⁴

The present study provides new tool to assess the anxiety and stress of pregnant woman on a pandemic. Despite its contributions, it presents some limitations that should be addressed. Since this is an online survey, face to face evaluation of the participants were missed. Pregnant women

who had smart phones and WhatsApp facility could only enrolled in this survey. So, this study lacks the response of those from remote areas where internet facility is not available. Hence, the results may not be generalizable to the target population of Kerala.

5 CONCLUSIONS

A 15-item scale (PASSP) is a validated short tool developed to measure the anxiety and stress among pregnant women during pandemic. To our knowledge, this is the first instrument for measuring anxiety and stress related to pandemic that pertain to pregnant women community. Even though this tool was developed during the COVID-19 pandemic, one can use this for any pandemic period. The study is continuing to generalize the results to a larger sample.

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ETHICS STATEMENT

The research described in this article was approved by the institutional Research Ethics Committee.

CONFLICTING INTERESTS

The author(s) declare that they no potential conflicts of interest

CONSENT TO PARTICIPATE Informed consent was obtained from all individual participants included in the study.

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