# Validity and Reliability of the 23-Item Preterm Birth Risk Assessment Scale

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## Abstract

Purpose: This study aimed to perform a psychometric evaluation of the preliminary preterm birth risk assessment scale (PBRAS-K) of 32-item. Method(s): There were 299 subjects, 167 in the exploratory factor analysis (EFA) group and 132 in the confirmatory factor analysis (CFA) group, who delivered before $37^{+0}$ weeks after having preterm symptoms and were admitted to high-risk pregnancy maternal-fetal intensive care units (MFICU). After an item reduction process in EFA, the psychometric property scales were assessed using SPSS 26, and CFA was accomplished using AMOS 27. Results: The Kaiser-Meyer-Olkin measure (KMO) and Bartlett's $\chi^2$ test of sphericity confirmed the adequacy of the sample for factor analysis (KMO = .81 (> .80), $\chi^2$ = 1841.38, $p$ < .001). The final version of the PBRAS-K was comprised of 23 items within seven dimensions. Factor analysis identified items explaining 65.9% of the total variance. The PBRAS-K had a mean score of 35.58 (±10.35) and showed a high internal consistency and satisfactory reliability with a Cronbach's alpha of .85. The PBRAS-K had a low correlation with risk scoring of preterm delivery (RPD) for discriminant validity (r = .45, $p$ < .001), a positive, high correlation with the Somatic Awareness Scale with Spontaneous Preterm Labor (SPL-SAS) for criterion validity (r = .65, $p$ < .001), and with pregnant stress for convergent validity (r = .57, $p$ < .001). RPD and SPL-SAS were moderately correlated (r = .53, $p$ < .001). Conclusion(s): The PBRAS-23-K is a valid and reliable instrument for assessing pregnant women's risk of preterm birth. Clinical nurses are encouraged to apply and obtain information for effective interventions in MFICU. This scale has meaningful results and reflects the voices of women who had a preterm birth. The scale should be evaluated for standardization and cut-off scores using larger subject sizes in the future.

Keywords: Factor Analysis, Statistical; Premature birth; Psychometrics; Scale development

## Introduction

Preterm birth (PTB) is defined as the birth of a baby before 37 weeks [1,2] and is the second most common cause of infant death in the United States (U.S.)[3]. Preterm babies may be born with serious health problems, some of which, like cerebral palsy, can be lifelong. Other problems, such as learning disabilities, may appear later in childhood or in adulthood. PTB is among the most complex and important challenges in obstetrics. Thus, clinicians and researchers have a keen interest in detecting women at high risk for PTB[4].

Many clinicians have tried to predict the incidence of PTB. However, predicting PTB is still difficult. Biomarkers such as interleukin 6 (IL-6), placental alpha microglobulin 1 (PAMG-1), and fetal fibronectin (fFN) have low positive predictive values (PPVs) and provide limited utility in the diagnostic algorithms most commonly used in the U.S. according to the American Association for Clinical Chemistry (AACC) guidance [3]. Approximately 50% of PTBs follow spontaneous preterm labor (sPTL), about 35% follow preterm pre-labor rupture of membranes (PPROM), and the remainder of PTBs are iatrogenic, caused by medically induced maternal or fetal complications [4,5]. About 50% of PTBs occur after natural PTL. Thus, if such PTL can be prevented, it will greatly contribute to reductions in PTB occurrence.

Predicting PTB would involve a screening test with high sensitivity and high negative predictive value. A wide variety of screening tools are classified into four groups: monitoring uterine activity, the assessment of cervical length, the measurement of cervical fetal fibronectin (fFN), and the presence of bacterial vaginosis in early pregnancy [5]. These screening tools are useful in the hospital, but an assessment scale that can be available for community-residing pregnant women has not been developed. There are only a few measurements to assess PTB or PTL. Creasy et al. developed a system for scoring the risk of preterm delivery (RPD) to predict spontaneous PTB. The RPD assessment was divided into four components: socioeconomic status, previous medical history, daily habits, and aspects of the current pregnancy. The RPD system was better for multigravida women, and rescoring at 26 to 28 weeks of gestation increased the predictive accuracy [6], but its overall predictive value was only 17 % – 34%. In contrast to RPD, the screening tool for PTB risk in Korea developed by Cho and Kim (2020) included the biomedical and somato-psychological risks of pregnant women [7]. In other words, it contained psychological questions that are not present in RPD assessments. Kim [8] identified nine components that included not only obstetrical and physical states and

medical problems but also life-related stress, pregnancy stress, spousal support, and information support. Looking more closely, PTL is a biopsychosocial process and does not occur in isolation because of individual factors, rather it is a combination of those factors that increase the risk of PTB [9]. The psychological risk factors for PTL are broad and diverse but have been shown to affect the rates of premature birth [10,11]. Cumulative stress was shown to increase the risk of PTL [12]. Family support is known to affect the rates of PTL and is generally considered a protective factor [13]. These previous findings indicate that bio-psycho-social stressors should be included when assessing PTL risk.

Therefore, a scale that can inform pregnant women about the causes of PTB needs to be developed. Based on nine components of PTL and PTB [8], the author developed a 32-item preliminary preterm birth risk assessment scale (PBRAS-32-K) [14]. The explanation of item generation and changes to create the final version from the first stage of scale development published previously were numerous and the process from item generation to preliminary tool development was explained in detail Accordingly, this study focused on the second stage of scale development, that is, the psychometric evaluation of the PBRAS-32-K, and presents the final 23-item version, PBRAS-23-K.

## Methodology

### Study design

The design of this methodological study was a cross-sectional survey aimed to evaluate the reliability and validity of the preliminary PBRAS-32-K scale [14] developed by DeVillis [15].

### Sampling

Off-line data collection was planned with postpartum women who had experienced PTL at each MFICU center but was changed to an online Google platform because of the COVID-19 pandemic. The participants provided informed consent to participate in the platform, verifying that they understood the purpose and content of the study. The sample size needed was over 300, or 5 – 10 times the number of exploratory factor analysis (EFA) items and five times the number of final CFA items [16]. The researcher adopted five times the number of items for both EFA and CFA in this study. Therefore, a minimum of 160 subjects were required for EFA and 115 subjects for CFA. Data collection was finished when sufficient sample numbers were accumulated. A total of 298 responses were used, 167 for the 32-item EFA and 131 for CFA, after excluding insufficient data. As a rule, to ensure construct validity, at least 10 participants are needed for each item of the scale, and to ensure construct validity and reliability, the data on a representative sample of the target

population should be collected [15].

**Ethical consideration**

This study was approved annually by the Institutional Review Board of the University in Korea [IRB No.:

1040875-201905-SB-026- 202001-SB-004-05(second year), 202101-SB-009-01(third year)].

**Statistical analysis of PBRAS-32-K psychometrics**

The PBRAS-32-K was developed according to the guidelines for scale development [15]. The details are

shown in Figure 1.

| Steps | Detailed contents |
|---|---|

| | | |
|---|---|---|
| **Preliminary instrument development*** | Development of items | Literature review, individual interviews/open questionnaire - Preliminary items: 108 |
| | Preliminary instrument development | 1st Preliminary item: Content validity test by experts 2nd Preliminary item: Content validity test by experts Pilot test by women with preterm birth |
| **Verification of instrument** | First evaluation of instrument | Main survey: 32 items - Exploratory factor analysis - Convergent validity - Criterion validity test - Discriminant validity test - Reliability test |
| | Second evaluation of instrument | Confirmatory factor analysis of 23 items |
| | Final instrument | Final instrument confirmation |

**Figure 1. Scale development process**
* Development process for preterm birth risk assessment scale in high-risk pregnancy: 1st phase of preliminary scale development J Korean Soc Matern Child Health 2022;26(3):1-12

Descriptive statistics and psychometrics of the reliability and validity tests were performed with SPSS

statistics version 27.0/AMOS 27.0. Descriptive statistics were used to determine the frequency, range, mean,

and standard deviation of the sample's demographic and clinical characteristics. All other tests were two-tailed,

and a *p*-value of less than 5% was considered statistically significant. Item analysis included the mean and standard deviation, skewness and kurtosis, and corrected item-total correlation coefficients. Absolute skewness and kurtosis values were evaluated to determine whether they were less than 3.0 for skewness and less than 7.0 for kurtosis, satisfying the item analysis conditions. Total scores and intra-item correlations were also analyzed to determine whether the values were ≥ .30 (if the same concept is measured by many items, a correlation coefficient of ≥ .30 is adequate)[17,18].

Psychometric analysis

EFA and CFA were performed for construct validity. Principal component factor analysis was performed as the factor extract model to minimize information loss from minimum-factor prediction, and varimax rotation was run to clearly classify the factors by maximizing the sum of the factor-loading variance. First, to confirm the appropriateness of the materials for EFA, the Kaiser-Mayer-Olkin (KMO) test and Bartlett's test of sphericity were performed [19]. The KMO measure of sampling adequacy was ≥ .5, indicating that the sample selection was adequate for factor analysis. Bartlett's Test of Sphericity confirmed patterned relationships among the variables, as seen in the correlation matrix (*p* < .001). Bartlett's test of sphericity tested the hypothesis that the correlation matrix was an identity matrix, which would indicate that the variables were unrelated, and, therefore, unsuitable for structure detection. Small significance level values (less than .05) indicate that factor analysis of the data may be useful [17].

For extracting factors through EFA, the number of factors was determined by the following criteria: an eigenvalue of 1 or above, factor loading ≥ .40 [19], and accumulative variance of 50 – 60.0% [20]. For CFA model verification, the goodness of fit coefficients, normed $\chi2$ ($\chi2/df$), the normed fit index (NFI), the relative fit index (RFI), the incremental fit index (IFI), the goodness of fit index (GFI), standardized root mean residual (SRMR), root mean square error of approximation (RMSEA), Tucker-Lewis index (TLI), and comparative fit index (CFI) were verified.

For convergent construct validity, the PBRAS-23-K was compared to pregnancy-related stress using Pearson's correlation coefficient because a previous study showed a moderate positive correlation between PTB screening [7] and pregnancy-related stress, and PTB was related to stress [12,21].

For discriminant validity [22], the PBRAS was compared to the RPD [6] scoring system as a gold standard used in obstetric studies because PBRAS measures different constructs than the RPD. RPD has four constructs, "socioeconomic status" (nine items), "previous medical history (nine items), "daily habits" (four items), and "aspects of current pregnancy (17 items). Cronbach's α was not reported.

Lastly, the criterion validity of the PBRAS was evaluated using the Somatic Awareness Scale with Spontaneous Preterm Labor (SPL-SAS)[23]. SPL-SAS has the constructs of "physical tension sensations" (15 items), "traditional PTL sensations" (nine items), "psychosomatic sensations" (six items), "sickness" (five items), "vaginal discharge" (five items), "gastrointestinal sensations" (three items), "gastrointestinal irritability" (three items), and "energy sensation" (one item), with a Cronbach's alpha of .94 [23]. Correlation was high at .6 (< r) [24].

## RESULTS

The general  characteristics of the participants and details are shown in Table 1.  A total of 299 women who delivered before $37^{+0}$ weeks after having preterm symptoms and were admitted to the high-risk pregnant intensive care unit were included in the study. The data from 298 subjects were analyzed, excluding the data of one subject because it was insufficient. The sociodemographic characteristics were as follows. The EFA subjects had a mean age of 34.4 (± 4.50) years, a height of 160.7 (± 5.53) cm, and a pre-pregnancy weight of 57.76 (± 11.32) kg. Their husband's mean age was 37.2 (± 5.03) years old. The CFA subjects had a mean age of 34.7 (± 4.32) years, a height of 161.5 (± 5.16) cm, and a pre-pregnancy weight of 60.59 (± 11.53) kg. Their husband's mean age was 37.1 (± 4.77) years. Seventy-five (45.5%) and 27 (16.2%) subjects in the EFA group had experience with PTB and PPROM, and 45 (34.4%) and 12 (9.2%) subjects in CFA, respectively, while PTB was expected in 31 (18.6%) subjects in the EFA group and 31 (23.8%) subjects in the CFA group (Table 1).

**Table 1.  Sociodemographic and Obstetric Characteristics (*N*=298)**

| Characteristics | Categories | 1st Survey (N=167) | 2nd Survey (N=131) |
|---|---|---|---|
| | | M ± SD or n (%) | M ± SD or n (%) |
| Woman's age (yr) | | 34.4 ± 4.50 | 34.7 ± 4.32 |
| Husband's age (yr) | | 37.2 ± 5.03 | 37.1 ± 4.77 |
| Education* | Middle junior | 2 (1.1) | 1(0.7) |
| | High school | 24 (14.4) | 38(29.0) |
| | University | 112 (67.1) | 82(62.7) |
| | Graduate school | 29 (17.4) | 10(7.6) |
| Woman's height (cm) | | 160.70 ± 5.53 | 161.5 ± 5.16 |
| Woman's pre-pregnancy weight (kg) | | 57.76 ± 11.32 | 60.59 ± 11.53 |
| Preterm birth (PTB) | No | 90 (54.5) | 86 (65.6) |
| | Yes | 75 (45.5) | 45 (34.4) |

| PPROM before PTB | No | 140(83.8) | 119(90.8) |
|---|---|---|---|
| | Yes | 27(16.2) | 12(9.2) |
| Expected PTB | No | 136(81.4) | 100(76.2) |
| | Yes | 31(18.6) | 31(23.8) |
| Absolute bed rest meaning by explanation | Know | 136(81.4) | 116(88.5) |
| | Didn't know | 31(18.6) | 15(11.5) |
| Enough information from health team | Dissatisfied | 31 (18.6) | 26(19.8) |
| | Satisfied | 136 (81.4) | 105(80.2) |
| Compliance instruction | No | 154 (92.2) | 122(83.1) |
| | Yes | 13 (7.8) | 9(6.9) |

## Construct validity

Psychometric analyses were accomplished by EFA, CFA, concurrent validity, discriminant validity, criterion validity, internal consistency, and item-total correlation.

### *KMO sampling adequacy and Bartlett's sphericity*

To assess construct validity, the researcher conducted EFA using 32 items for 167 pregnant women. First, sampling adequacy was evaluated by the KMO measure and Bartlett's $\chi^2$ test of sphericity, which confirmed that this sample was adequate for factor analysis [25] (KMO = .81 (> .80), $\chi^2$ = 1841.38, $p$ < .001). The number of factors was determined by a scree plot and the minimum average partial because the Kaiser rule tends to severely overestimate the number of factors. EFA showed nine factors.

The absolute skewness and kurtosis values were normally distributed. All absolute values were less than 3.0 for skewness (0.2~1.41) and less than 7.0 for kurtosis (0.10~1.62), satisfying the item analysis conditions.

### *Item communality*

The communality cut-off value 0.30 was  applied, and the 32 items were evaluated as sufficient. Values viewed with the factor correlation matrix were often less than .15. First, principal component analysis, varimax rotation with an eigenvalue limitation (> 1.0), the maximum likelihood method, and a scree plot were performed. Then principal axis factoring and promax rotation programs were run, but promax rotation was not fit in this study. Finally, principal component analysis, varimax rotation and a scree plot were used to generate adequate factor numbers.

When performing EFA using principal axis factoring with promax rotation, Osborne et al (2008) suggested

that communalities above 0.4 are acceptable [26]. The number of factors was determined by a scree plot and the minimum average partial. The first 32-item EFA showed nine factors, and the cumulative explanation was 63.5%.

### Item reduction by combined EFA and CFA

To get the most adequate value of explanatory power with factor numbers, EFA was run several times and got the powerful explanation at fifth EFA. When program was run using a factor number of 167 women, the communality of seven items (Q5, Q9, Q12, Q16, Q17, Q18, and Q32) among all 32 items (< .40 eigen values) was removed (Q5: Bloody discharge from the vagina, Q9: My belly was sorely sick, Q12: My groin seemed to fall out, Q16: Lying down was stuffy, so I wandered around a bit, Q17: It was difficult to stand on the bus or train when commuting, Q18: Because a friend or relative came to the house, it made it difficult to clean or prepare food, and Q32: I was stressed because I couldn't walk).

Next, EFA was conducted by varimax rotation again using the remaining 25 items, and Q4 (Something like a runny nose came out of the vagina) ( < .40 eigenvalue) was excluded. Twenty-four items and seven factors explained 63.4% of the total variance. EFA was conducted several more times, and six factors explained 60.3% (KMO = .797, $\chi^2$ = 1363.77,  $p$ < .001), four factors explained 49.6%, and three factors explained 42.9% of the variance. Through the EFA evaluation, seven factors satisfied KMO (> .80) and the cumulative explanation of variance (> 60%). Varimax rotation was conducted again using 24 items and Q19 (When the contractions of the uterus disappeared, I went home) only valued at .41 (< .50 eigenvalue) was also excluded. Finally, seven factors and 23 items explained 65.9% of the variance of and 167 subjects satisfied the sampling adequacy for factor analysis (KMO) and Bartlett's sphericity [KMO = .805, $\chi^2$ = 1322.52, DF 253, $p$ < .001) ] (Table 2).

**Table 2. Fifth Factor Analysis of PBRAS-K (seven factors, 23 items)** *(N=167).*

| Item No. | Communality | F1 | F2 | F3 | F4 | F5 | F6 | F7 | Skewness | Kurtosis |
|---|---|---|---|---|---|---|---|---|---|---|
| Q25 | .754 | .858 | .050 | .106 | -.079 | .078 | -.030 | -.029 | -.72 | -.73 |
| Q22 | .646 | .730 | .145 | -.036 | .179 | .057 | .091 | .128 | .89 | .79 |
| Q23 | .633 | .725 | .135 | -.073 | .009 | -.148 | -.001 | .206 | -1.22 | .35 |
| Q26 | .556 | .701 | .132 | .242 | .005 | .026 | .000 | -.017 | -.14 | -1.01 |
| Q24 | .596 | .638 | .003 | .160 | .078 | .122 | .026 | -.303 | -.02 | -1.62 |
| Q20 | .730 | .062 | .811 | .062 | .147 | .217 | .001 | -.100 | .09 | -1.05 |

| Item | | F1 | F2 | F3 | F4 | F5 | F6 | F7 | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Q13 | .740 | .108 | .768 | .307 | .158 | -.030 | .104 | .001 | -.16 | -.72 |
| Q15 | .652 | .161 | .752 | .048 | .081 | .105 | -.029 | .047 | -.41 | -.48 |
| Q14 | .709 | .160 | .704 | .329 | .146 | -.009 | .240 | .059 | -.23 | -.64 |
| Q29 | .589 | .079 | .186 | .831 | .120 | -.066 | .175 | -.084 | -.12 | -.95 |
| Q31 | .761 | .150 | .265 | .771 | .154 | .034 | .196 | -.007 | .02 | -1.13 |
| Q27 | .733 | .121 | .118 | .720 | -.007 | .249 | -.246 | .207 | .56 | -.80 |
| Q7 | .655 | .127 | .133 | -.071 | .782 | -.009 | -.093 | .216 | -.77 | .37 |
| Q11 | .672 | -.069 | .155 | .086 | .687 | .281 | .107 | -.098 | -.09 | -.94 |
| Q8 | .739 | .034 | .332 | .238 | .606 | .113 | .180 | .122 | -.18 | -.86 |
| Q10 | .689 | .161 | -.008 | .212 | .518 | .480 | .271 | -.152 | .96 | -.10 |
| Q1 | .568 | -.031 | .074 | -.002 | -.011 | .790 | .102 | .124 | .78 | -.72 |
| Q21 | .625 | .126 | .166 | .193 | .380 | .632 | .168 | -.123 | 1.18 | .81 |
| Q3 | .543 | .022 | .056 | .010 | .128 | .625 | -.043 | -.046 | 1.41 | 1.10 |
| Q2 | .684 | .111 | .209 | .252 | -.101 | .198 | .769 | -.032 | -.11 | -.89 |
| Q6 | .634 | -.048 | .008 | -.081 | .269 | .012 | .697 | .194 | -.94 | .87 |
| Q30 | .526 | .039 | -.069 | .034 | .175 | -.064 | .166 | .777 | -.87 | -.21 |
| Q28 | .589 | .053 | .252 | .434 | -.214 | .323 | -.106 | .483 | .38 | -1.24 |
| Eigenvalue | | 5.71 | 2.47 | 1.90 | 1.55 | 1.32 | 1.16 | 1.06 | | |
| Explained variance | | 12.55 | 12.11 | 10.98 | 9.55 | 8.94 | 6.48 | 5.31 | | |
| Cumulative explained variance | | 12.55 | 24.66 | 35.64 | 45.19 | 54.13 | 60.61 | 65.91 | | |
| Number of items | | 5 | 4 | 3 | 4 | 3 | 2 | 2 | | |

## Model fit

In this study, the fit of seven factors and 23 item explained PTB risk (RMSEA = .043, NFI = .831, RFI = .746, IFI = .954, TLI = .925, and CFI = .950) (Table 3).

**Table 3. Model Fit of 23 Items**

| Model | RMSEA | NFI | RFI | IFI | TLI | CFI |
|---|---|---|---|---|---|---|
| Default model | .043 | .831 | .746 | .954 | .925 | .950 |

## Reliability for internal consistency

Reliability was tested to select the final 23 items. Cronbach's alpha for internal consistency was .85, with

the high value reflecting that it was the first scale developed. The 23 items had a mean of 34.08 ± 10.33 (N = 167, F = 61.71, $p$ < .001). The mean CFA score of the PBRAS-23-K (N = 131) was slightly higher (36.88 ± 10.80) than that of EFA (N = 167). The PBRAS-23-K showed a high internal consistency and satisfactory reliability with a Cronbach's alpha of .85, and the total mean ± SD of the PBRAS-23-K was 35.58 ± 10.35 in 298 subjects. The internal consistency of the PBRAS-23-K showed a corrected item-total correlation of the other items of over .30 except for five items [Q1 (.26), Q3 (.23), Q6 (.17), Q23 (.28), and Q30 (.11)]. However, Cronbach's α was not increased above .85 even if these five items were deleted, and reliability of the subscales was .60 ~ .83, except for factor 6 (.44) and factor 7 (.20). Therefore, in this study all 23 items were retained (Table 4). The final version of the PBRAS-K was comprised of 23 items (Supplement 1). Supplement 2 showed the internal consistency of each item. Supplement 3 showed seven dimensions of the PBRAS-23-K. Each item in the PBRAS-23-K was scored from 0 to 3 by considering that a typical respondent was at or near the center of the Likert scale according to DeVellis [15]. The total score is used to determine a woman's PTB risk level.

**Table 4. Internal Consistency of the PBRAS-23-K (*N*=298)**

|  | PBRAS-K items | Corrected item-total correlation | | Cronbach's α if item deleted | |
|---|---|---|---|---|---|
|  |  | N=167 | N=298 | N=167 | N=298 |
| Q1 | 1. I have anemia (hemoglobin level lower than 10 g/dL). | .26 | .24 | .85 | .85 |
| Q2 | 2. I feel depressed. | .34 | .47 | .84 | .84 |
| Q3 | 3. I don't take the prescribed medication. | .23 | .20 | .85 | .85 |
| Q6 | 4. I cannot sleep well. | .17 | .23 | .85 | .85 |
| Q7 | 5. My belly feels tight and hard often. | .31 | .31 | .84 | .84 |
| Q8 | 6. I feel pelvic pressure. | .53 | .51 | .84 | .84 |
| Q10 | 7. I feel deep penetrating pain. | .49 | .48 | .84 | .84 |
| Q11 | 8. I have dull pain in my back and belly. | .37 | .41 | .84 | .84 |
| Q13 | 9. I have lots of stress (at home/work). | .57 | ,59 | .83 | .83 |
| Q14 | 10. I feel very sensitive (at home/work). | **.62** | .59 | .83 | .83 |
| Q15 | 11. It is hard to work on my feet (at home/work). | .47 | .48 | .84 | .84 |
| Q20 | 12. I have too heavy of a workload (at home/work). | .50 | .49 | .84 | .84 |
| Q21 | 13. I have intense muscle pain. | .55 | .56 | .84 | .84 |
| Q22 | 14. I'm worried about my baby being born too early. | .44 | .40 | .84 | .84 |
| Q23 | 15. I try to hang tight even for one more day for my baby. | .28 | .27 | .84 | .85 |
| Q24 | 16. I feel nervous to hear that I have a short cervix. | .34 | .29 | .84 | .85 |
| Q25 | 17. I feel sad to hear that I could have preterm labor. | .39 | .42 | .84 | .84 |
| Q26 | 18. I get stressed by hearing negative things from my doctor. | .44 | .38 | .84 | .84 |
| Q27 | 19. I feel stressed by being responsible for all of the housework. | .43 | .47 | .84 | .84 |
| Q28 | 20. I rest fewer than two hours a day. | .33 | .34 | .84 | .84 |

| Q29 | 21. I get annoyed at my husband from time to time. | .49 | .52 | .84 | .84 |
| Q30 | 22. I eat fewer than four times a day. | .11 | .18 | .85 | .85 |
| Q31 | 23. What I want from my husband is not to do anything but to just listen to me, but I am sad he doesn't understand it. | .60 | .55 | .83 | .84 |

N=167: Cronbach's alpha = .85 (mean ± SD = 33.98 ± 10.43) (item mean = 1.48)
N=131: Cronbach's alpha=.85 (mean ± SD = 36.88 ± 10.80
N=298: Cronbach's alpha = .85 (mean ± SD = 35.58 ± 10.35) (item mean = 1.55)

Cronbach's alpha = .84 (mean ± SD = 30.58 ± 9.21) (item mean = 1.53) for 20 items with Q3, Q6, and Q30 excluded.

### Convergent validity and criterion validity for construct validity

Validity was compared between the SPL-SAS and pregnancy stress. In convergent validity, the PBRAS-23-K showed a significant moderate correlation with pregnancy stress ($r = .57$, $p < .001$), indicating the high validity of the similar construct. The PBRAS-23-K showed a low or moderate positive correlation [24] using RPD as criterion ($r = .45$, $p < .001$)

As criterion validity, it was evaluated with SPL-SAS was evaluated for somatic symptoms, and a high correlation coefficient $r = .65$ ($p < .001$) was found (Table 5).

**Table 5. Criterion and Discriminant Validity** *(N=298)*

| Scales | SPL-SAS | High-risk pregnancy stress | RPD | PBRAS-23-K |
|---|---|---|---|---|
| | r (*p*) | r (*p*) | r (*p*) | |
| SPL-SAS | 1 | | | |
| High-risk pregnancy stress | .47 (<.001) | 1 | | |
| RPD | .53 (<.001) | -.29 (.001) | 1 | |
| PBRAS-23-K | .65 (<.001) | .57 (<.001) | .45 (<.001) | 1 |

PBRAS, preterm birth risk assessment scale; RPD, risk for preterm delivery; RPD, risk scoring for preterm delivery; SPL-SAS, the Somatic Awareness Scale with Spontaneous Preterm Labor

## Discussion

Measurement is a fundamental activity of science [27] and measurement scales are useful in evaluating

attributes that cannot be measured directly. In the case of the psychosocial attributes of stress or depression, the magnitude cannot be directly measured, although pain can be calculated to some extent. In tool development research, it is necessary to plan the research by first deciding whether to perform only EFA or CFA. EFA is data-driven and involves a number of subjective decisions. Thus, a more appropriate way to cross-validate the factor structure of a test is by CFA. The basic question answered by CFA is whether the factor structure matches the results of the original study [41].

For our knowledge, the structure of the PTB-related variables and the relationship between them have not been proven yet. However, a few studies on the predisposing factors of PTB have been conducted. Maloni reported behavioral, environmental, demographic, medical, and reproductive factors [28]. Creasy et al. (1980) classified the socioeconomic status, previous medical history, daily habits, and aspects of the current pregnancy in their RPD [6], but they did not explain the concepts or theories of PTB or PTL. Klockars-McMullen (2014) developed a scale based on the symptom perception model (SPM) by Gijsbers van Wijk and Kolk (1997) who integrated the concepts of environment, experience, emotions, and other psychological variables into their model of symptom perception [23]. Moreover, to date, few studies have actually utilized an integrative biopsychosocial model, but only recommend its use in future studies [29, 30]. Social support, educational attainment, gestational diabetes, preeclampsia, barriers to healthcare, and psychopathology represent unidirectional pathways to PTL [31]. Hoyman (2016) tested an integrative biopsychosocial model for PTL in the Hispanic mothers of twins, and preeclampsia, the number of prenatal care visits, prenatal emotional problems, and an additional variable, primipara, predicted PTL [32]. However, this model was biased for biomedical variables such as preeclampsia, prenatal care visit number, and primipara. Therefore, this model is not suitable for primigravida or pregnancy without preeclampsia. The above findings did not establish PTB or PTL theories, so this study focused on combined EFA and CFA. EFA only or CFA with the same sample is possible [33], so the author adopted a 0.5:1 ratio.

Other factors involved in PTB should also be reviewed. Kim (2020) visualized nine components to explain PTB [14]. In this study, the first 32-item EFA showed nine factors and the cumulative explanation was 64.3% (KMO = .81 (> .80), $\chi^2$ = 1841.38, $p$ < .001). However, five repeated EFAs with reduced numbers of items, and a scree plot clearly showed seven factors and 23 items. Also from the perspective of item-total item correlation, the correlation coefficient of item–total correlation coefficient was lower than .15, indicating that this scale might not be the complete version. Therefore, testing with various other sample groups is necessary. In this study, the fit of seven factors and 23 items of the PBRAS-K explained PTB risk (RMSEA = .043, NFI = .831, IFI = .746, IFI = .954, TLI = .925, and CFI = .950). Therefore, the PBRAS-23-K 23 was evaluated as valid and reliable in this evaluation stage.

Pregnant women with PTL are at risk of giving birth soon, so they are hospitalized in the MFICU and managed. In the MFICU, the patient is required to rest and is administered an anti-contraction drug to prevent the progress of labor. They are discharged when the uterine contractions disappear. While admitted, women with PTL are not concerned with the hard work they did at home (workplace) or how stressed they were. However, when they go home, they are in a similar stressful situation again, and many return to the hospital urgently in a few days.

Reliability

In this study, the internal consistency showed a Cronbach's alpha of .85 for the total items, indicating an adequate instrument [34]. Also, the PBRAS-23-K retained items r < 0.3 (corrected item-total correlation) for broad measurements. Clark & Watson (1995) suggested that item-total correlation (0.15~0.20) items should be selected for broad measurements, and recommended items more than 0.40 for narrow measurements [35]. In the subscales, factors 1, 2, 3, and 4 were reliable, but factor 6 was .44 and factor 7 was .20. These two factors and four items did not impact internal consistency.  Although factors composing small items might have low reliability [33], the PBRAS-23-K should be studied with larger sample sizes.

Validity

In this study, the PBRAS-23-K showed high validity with a similar construct as high-risk pregnancy stress assessment (r =.57, *p* <.001) and a low-to-moderate positive correlation [24] with RPD (r = .45, *p* < .001). Rea & Parker reported that an r-value (0.4 – 0.6) indicated a moderately strong positive relationship [34], although evaluations might differ slightly between researchers. This PBRAS-K also showed a high correlation with SPL-SAS for somatic symptoms (correlation coefficient r = .65, *p* < .001). Except for Q28 (r = .48), a particular construct correlated with other tests that assessed the same construct (≥ .50), and a particular construct did not correlate with tests that measured different constructs (< .33). That is, the PBRAS-23-K had high convergence validity and discriminant validity.

Number of items per factor

Although the factor structure started with nine components, a good tool is recommended to consist of three or more items for each factor [36]. However, subscales including a single item are also used. It is necessary to discuss the number of items in one factor [37]. Repeated studies are required with more sample groups.

In addition, it is necessary to conduct additional research with more subjects to see if it would have been better to exclude according to the criteria, even if it had a slight effect on the overall reliability of Q1, Q3, Q6, Q23, and Q30, which remains an important methodological discussion.

Scoring

Each item in the PBRAS-23-K was scored from 0 to 3, and the total score was used to determine a woman's level of PTB risk according to DeVellis [15]. However, the degree of PTB risk was not analyzed. Therefore, PBRAS-K cutoff scores for minimal, mild, moderate, and severe PTB risk needs to be established in future studies.

Limitations

In this study, the researcher adopted a minimum sample size for CFA of five times the number of items based on a previous study [33]. In this study, a sample size of 167 for 32-item EFA and a sample size of 132 for 23-item CFA were found to be suitable. The item-total item correlation was over 0.3 in this study. So the ratio of sample size and total items was about 5, and it was reasonable to use this ratio.

The sample size is also not consistent among researchers, and larger samples are required for more stable scales [36]. For a more rigid CFA evaluation, using sample sizes larger than the general rule might be necessary.

It is also necessary to repeat and explore the optimal reduced number of observed variables.


Implications

The PBRAS-23-K was developed with seven factors based on a previous study reporting that PTB had nine components. This scale should be further simplified for clinical nurses and public nurses to counsel, educate, and care for women with PTB risk..


Conclusions

The PBRAS-23-K is a valid and reliable instrument for assessing pregnant women's risk of PTB. Clinical nurses are encouraged to apply and obtain information for effective interventions in MFICUs. This scale has meaningful results and reflects the voices of women who had PTB. The scale should be evaluated for standardization and cut-off scores using larger subject sizes in the future.

Data availability Yes.


Declarations

Conflict of interest The authors have no conflicts of interest or any competing interests to declare.


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**Supplement 1. The Preterm Birth Risk Assessment Scale-Korean Version [PBRAS-23-K]**

We would like to evaluate the preterm labor risk by assessing what symptom(s) you experienced *during your pregnancy*, specifically from the 20th week of pregnancy to labor.
Please check **V** for the following questions that apply to you.

| Questions | Never (0) | Rarely (1) | Sometimes (2) | Often (3) |
|---|---|---|---|---|
| 1. I have anemia (hemoglobin level lower than 10 g/dL). | | | | |
| 2. I feel depressed. | | | | |
| 3. I don't take the prescribed medication. | | | | |
| 4. I cannot sleep well. | | | | |
| 5. My belly feels tight and hard often. | | | | |
| 6. I feel pelvic pressure. | | | | |
| 7. I feel deep penetrating pain. | | | | |
| 8. I have dull pain in my back and belly. | | | | |
| 9. I have lots of stress (at home/work). | | | | |
| 10. I feel very sensitive (at home/work). | | | | |
| 11. It is hard to work on my feet (at home/work). | | | | |
| 12. I have too heavy of a workload (at home/work). | | | | |
| 13. I have intense muscle pain. | | | | |
| 14. I'm worried about the baby being born too early. | | | | |
| 15. I try to hang tight even for one more day for my baby. | | | | |

| | |
|---|---|
| 16. I feel nervous to hear that I have a short cervix. | |
| 17. I feel sad to hear that I could have preterm labor. | |
| 18. I get stressed by hearing negative things from my doctor. | |
| 19. I feel stressed by being responsible for all of the housework. | |
| 20. I rest fewer than two hours a day. | |
| 21. I get annoyed at my husband from time to time. | |
| 22. I eat fewer than four times a day. | |
| 23. What I want from my husband is not to do anything but to just listen to me, but I am sad he doesn't understand it. | |

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| Supplement 2. Internal Consistency of Each Factor | | | | |
|---|---|---|---|---|
| Factor | Number of items (item number) | Mean ± SD | Item mean ± variance | Cronbach's α |
| 1 | 5 (22, 23, 24, 25, 26) | 9.34±3.86 | 1.87 ±1.09 | .80 |
| 2 | 4 (13, 14, 15, 20) | 9.04±3.01 | 1.57± 0.85 | .83 |
| 3 | 3 (27, 29, 31) | 3.83±2.46 | 1.28±0.97 | .78 |
| 4 | 4 (7, 8, 10, 11) | 5.70±2.65 | 1.43±0.81 | .72 |
| 5 | 3 (1, 3, 21) | 1.91±1.92 | 0.64±0.73 | .61 |
| 6 | 2 (2, 6) | 3.56±1.34 | 1.78±0.70 | .44 |
| 7 | 2 (28, 30) | 3.38±1.52 | 1.69±1.03 | .20 |
| Total | 23 | 33.98±10.43 | 1.48±0.90 | .85 |
| SD: standard deviation | | | | |
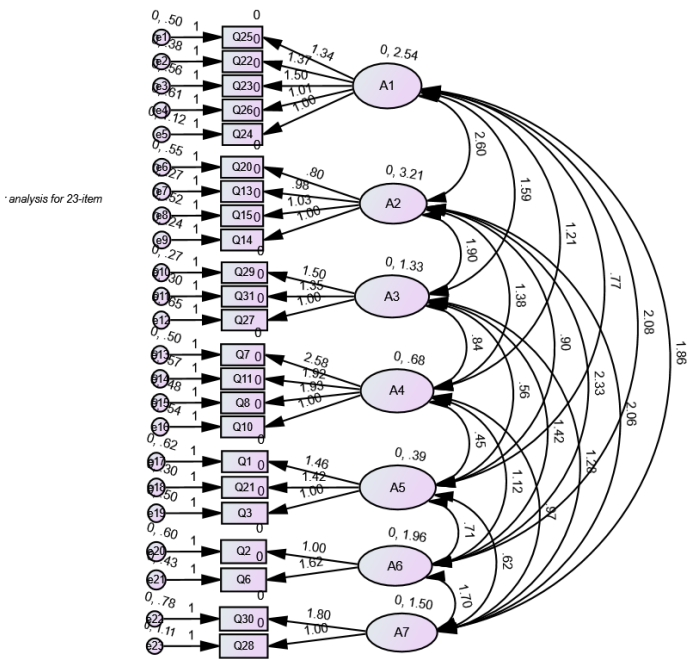
Supplement 3. Confirmatory factor analysis