Advances in Reproductive Sciences, 2025, 13(3), 180-198
https://www.scirp.org/journal/arsci
ISSN Online: 2330-0752
ISSN Print: 2330-0744

The Pregnancy-Unique Quantification of Emesis: Its Clinical Correlates and Severity Ranking among Japanese First Trimester Pregnant Women

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How to cite this paper: Hada, A., Minatani, M., Wakamatsu, M. and Kitamura, T. (2025) The Pregnancy-Unique Quantification of Emesis: Its Clinical Correlates and Severity Ranking among Japanese First Trimester Pregnant Women. *Advances in Reproductive Sciences*, **13**, 180-198.
https://doi.org/10.4236/arsci.2025.133016

Received: July 19, 2025
Accepted: August 23, 2025
Published: August 26, 2025

Abstract

Background: Nausea and vomiting (emesis) is one of the commonest symptoms during pregnancy. The Pregnancy Unique Quantification of Emesis (PUQE: Koren *et al.*, 2002) is one of the most widely used measures of emesis. **Aim:** To validate the 24-hour version of the PUQE (PUQE-24) in a population of pregnant Japanese women. A second aim was to identify the severity ranking of PUQE-24 scores. **Methods:** Approximately 1,500 pregnant women at gestational weeks before 20 were recruited for antenatal checkups at a general hospital and five private clinics in the Tokyo metropolitan area and Kagoshima Prefecture in Japan from January 2017 to May 2019. About a quarter (n = 378) of the participants responded to the questionnaire. They were distributed a set of questionnaires, including the PUQE-24. **Results:** PUQE-24 scores significantly correlated with younger gestational age, scores on the Health-Related Quality of Life for Nausea and Vomiting during Pregnancy, reduced changes in fluid and meal intake, Sheehan Disability Scale, and depression scores. A two-step cluster analysis with a fixed number of clusters at 4 yielded four groups: Severe, Moderate, Mild, and No Symptoms. Receiver operating characteristic (ROC) analysis produced the best cutoff points for these four

groups (3/4, 6/7, and 7/8). They reported excellent specificity, sensitivity, and positive and negative predictive values. **Conclusion:** Our findings indicate that a cutoff point of 6/7 may be suitable for clinical uses in pregnant women.

Keywords

Pregnancy-Unique Quantification of Emesis (PUQE), Validity, Severity

1. Introduction

Nausea and vomiting (also known as emesis) is one of the commonest symptoms during pregnancy. The prevalence of emesis, as reported by a prospective study in England, was 80%, with 28% experiencing only nausea and 52% experiencing both nausea and vomiting [1]. The quality of life of pregnant women is substantially reduced [2] [3]. Hyperemesis gravidarum (HG) is a severe form of emesis; however, its diagnostic criteria have not yet reached an agreement [4]. A quarter of HG cases persist throughout pregnancy [5]. Emesis and HG in particular are associated with poor delivery outcomes such as premature birth [5] and termination of pregnancy [6] as well poor child development [7]. Emesis is also associated with higher prevalence of mental health problems before and during pregnancy as well after childbirth such as depression [8]-[15], anxiety [11] [14]-[16], obsessive-compulsive disorder [14], tokophobia [17], posttraumatic stress disorder [18]-[20] and others [21] [22].

Among several self-report measures of emesis [23]-[27], the Pregnancy Unique Quantification of Emesis (PUQE: Koren *et al.*, 2002 [28]) is one of the most widely used tools (e.g., Birkeland *et al.*, 2015; Koren & Cohen, 2020; Yilmaz *et al.*, 2022 [29]-[31]). The PUQE was recommended by the American College of Obstetricians and Gynecologists (2018) [32], National Institute for Health and Care Excellence (2021) [33], French College of Gynecologists and Obstetricians [34], and Society of Obstetric Medicine of Australia and New Zealand [35]. Its 24-hour version PUQE-24 (Ebrahimi *et al.*, 2009 [36]) has only three items with a 5-point scale: nausea, vomiting and retching for the previous 24 hours. Its total score ranges from 3 to 15 with higher scores indicating more severe emesis. The PUQE-24 was translated into Japanese by Kitamura and colleagues after obtaining the permission from the original author and Hada *et al.* reported its configural, measurement, and structural invariance between nulliparas and multiparas and across two measurement time points [37]. There may be no debatable points about content validity of the PUQE-24 because emesis consists of nausea and vomiting together with retching when there is no food or fluid to vomit. However, its criterion validity is yet to be studied in detail. Criterion validity is based on correlations with an accepted standard. In this study, we expected that the PUQE-24 score would be associated with other measures of emesis such as the Health-Related Quality of Life for Nausea and Vomiting during Pregnancy (NVPQOL; Magee, *et*

al., 2002 [24]) as well as clinical measures including reduced water and meal intake, reduced urinary frequency, and treatment for emesis as well social dysfunction. Construct validity is based on the conceptual variable underlying a test. We expected, in this study, that the PUQE-24 scores would be associated with the severity of psychiatric symptoms including depression and insomnia. The first aim of this study is, thus, to study the validity of the PUQE-24 among Japanese pregnant women.

A conventional ranking suggests 3 - 6 points as "mild", 7 - 12 points as "moderate", and 13 - 15 points as "severe" [38]. Classification of pregnant women into a small number of categories is a clinical convention that is useful in practice. These findings provide guidelines for perinatal healthcare professionals. However, whether these cutoff points are applicable to the Japanese population remains unknown. Suitable cutoff points for patient-rated symptom measures may differ between countries and cultures. A second aim of the present study is to identify severity rankings of the instrument in a Japanese population. We used a cluster analysis with a fixed number of clusters of four. Reasonable cutoff points for the total PUQE-24 scores may be identified using receiver operating characteristic (ROC) curve analysis.

2. Methods

2.1. Study Procedures and Participants

Data used in this study were obtained from previous studies [3] [37] [39]-[41]. Emesis typically has its onset between the 4th and 7th week of pregnancy, peaks around the 9th week and results in cessation of symptoms in 90% of women by the 20th week (RCOG Green-top Guideline No. 6) [42]. For this study, approximately 1,500 pregnant women at gestational weeks before age 20 were recruited for antenatal checkups at a general hospital and five private clinics in the Tokyo metropolitan area and Kagoshima Prefecture in Japan from January 2017 to May 2019. The exclusion criteria for recruitment were: 1) insufficient fluency in Japanese, 2) age < 20 years, 3) history of an eating disorder, 4) symptoms of vaginal bleeding or abdominal pain, 5) history of subchorionic haematoma, and 6) recurrent miscarriages.

2.2. Measurements

24 hour Pregnancy-unique Quantification of Emesis and Nausea (PUQE-24; Ebrahimi Maltepe, Bournissen, & Koren, 2009 [36]): The PUQE-24 has three items to measure nausea, vomiting, and retching. The scores were rated as the daily number of vomiting episodes, duration of nausea per day in hours, and number of retching episodes per 24 h. The PUQE-24 score ranged from 1 to 5 for each category. The total score ranged from 3 to 15. Higher scores indicated more severe symptomatology. The PUQE-24 was translated into Japanese by M.M. and T.K. after obtaining permission from the original author. The bilingual author (T.K.) back-translated the text and compared it with the original English.

Health-Related Quality of Life for Nausea and Vomiting during Pregnancy (NVPQOL; [24]): The NVPQOL is a specific measure shown to be reliable and valid in a population of women reporting emesis during pregnancy. The NVPQOL contains 30 items and measures the QOL in the previous week. The scores ranged from 1 to 7 for each item. The total NVPQOL scores ranged from 30 to 210. Lower scores corresponded to better QOL. Yamada *et al.* (2020) examined the psychometric properties of the Japanese version of the NVPQOL and identified a one-factor structure [41].

Fluid and food intake and urinary frequency: Daily fluid intake was asked by a single item: "How much fluid did you drink each day in the past week?" in millilitres.

Change in fluid or meal intake was assessed by a single item: "How does your fluid or food intake in the past week compare with your pre-pregnancy intake?" This was rated on a 7-point scale (1 = extremely reduced, 2 = reduced, 3 = slightly reduced, 4 = unchanged, 5 = slightly increased, 6 = increased, and 7 = extremely increased). Urinary frequency in the past week was assessed using a single item: "How many times did you urinate in a day in the past week?".

Treatment of emesis: We asked about the outpatient visits and inpatient admissions for emesis. We scored 1 = none, 2 = outpatient visits, and 3 = inpatient admissions.

The Sheehan Disability Scale (SDS; © Copyright 1983-2020 Sheehan DV. All rights

reserved. May be reproduced only with the permission of Dr. David V. Sheehan, copyright holder. For permission contact davidsheehan@gmail.com) [43]. The SDS is a self-report measure consisting of three items. The SDS measures disabilities in the following three domains: 1) work and schoolwork, 2) social and leisure activities, and 3) family life and home responsibilities. Each item was rated from 0 to 10. Higher scores indicate better adjustment. We used the Japanese version of the SDS [44]. Hada *et al.* used the Japanese version of the SDS to measure pregnancy-related disabilities in expectant Japanese women [37].

Patient Health Questionnaure-9 (PHQ-9; Spizer, 1999 [45]): The PHQ-9 is a self-report measure of depression. Nine items check for the frequency of depressive symptoms over the previous two weeks and are rated on a four-point Likert scale from 0 to 3. Higher scores indicated more severe symptomatology. The Japanese version of the PHQ-9 [46] [47] was used for assessing depression. The Japanese version of the PHQ-9 has a two-factor bifactor structure (*i.e.*, the first, second, and general factors). The first factor reflected sleep change, fatigue, and appetite change. Thus, it was considered a somatic factor. The second factor reflected loss of interest, depressed mood, self-blame, concentration difficulty, psychomotor symptoms, and suicidality. Thus, it was considered a non-somatic factor. The general factor includes all items and reflects depression severity [40].

Insomnia Severity Index (ISI; Bastien *et al.*, 2001[48]). The ISI was used to measure the severity of insomnia. The ISI is a self-reported measure consisting of

seven items rated from 0 (no problem) to 4 (very severe). The total scores ranged from 0 to 28. Shinohara *et al.* (2022) reported the two-factor structure of the ISI in a sample of pregnant Japanese women [39]. The first factor represents early, middle, and late insomnia and sleep dissatisfaction. The second factor represents interference of insomnia-induced difficulties with daytime functioning, noticeable sleep problems, and concerns about sleep problems. The measurement invariance was also confirmed.

2.3. Data Analysis

First, Little's Missing Completely at Random (MCAR) test was used to examine the characteristics of the missing values across all variables. Thereafter, the mean, standard deviation (SD), and skewness for continuous variables, and frequencies for nominal variables were calculated. All cases were classified into the severity ranking categories of the PUQE-24 according to original classification (*i.e.*, None = 3, Mild = 4 - 6, Moderate = 7 - 12, and Severe = 13 - 15) scores, of which mean (SD) scores were calculated. The PUQE-24 score also correlated with other variables.

Next, we performed a two-step cluster analysis of the participants using their scores on the three PUQE-24 items. Cluster analysis divides cases into groups that are internally homogeneous and externally heterogeneous based on relevant characteristics [49]. The three items of the PUQE-24 were used as indicators for two-step cluster analysis. The cluster number was set to four because our aim was to identify the severity rankings of the instrument corresponding to the conventions of None, Mild, Moderate and Severe. To clarify the characteristics of the emerging clusters, those belonging to the four clusters were compared in terms of the variables studied. We set the alpha level (possibility of a Type I error) at $p < 0.001$ because of multiple comparisons.

To identify the most suitable cutoff points for the total PUQE-24 scores (between None and Mild/Moderate/Severe, None/Mild and Moderate/Severe, and None/Mild/Moderate and Severe), we performed a receiver operating characteristic (ROC) analysis [50] [51]. The accuracy of prediction based on the PUQE-24 score was examined in terms of specificity, sensitivity, and positive and negative predictive values with a range of cutoff points. The optimal cutoff points balanced psychometric properties and clinical utility.

3. Results

Of the pregnant women eligible for the study, 382 (approximately 25%) women participated in this study. Three cases were missing gestational weeks, and one case was at 22 weeks of gestation. Therefore, these four cases were excluded from the statistical analyses ($N = 378$). Of these, 139 (37%) were nulliparae, and 239 (63%) were multiparae. Parity was unknown in only four cases. Approximately half of the participants were employed (**Table S1**). Eighty-four (22%) had experiences with assisted reproductive technology. The mean, SD, skewness, and kurtosis of the continuous variables are shown in **Table 1**. While skewness for the SDS

total score (7.06) and kurtosis for the vomiting item of the PUQE-24 (9.64) were high, the other variables were within an acceptable range, indicating a normal distribution of the variables (Table 1). Little's Missing Completely at Random (MCAR) test showed that the data were missing completely at random: χ^2 (*df*) = 2737.479 (2679) (p = 0.211). Therefore, missing values were treated with list-wise deletions (see *n* in each Table).

Table 1. Mean, SD, skewness, and kurtosis for continuous variables (N = 378).

Variable	*n*	Mean	SD	Skewness	Kurtosis
Demographics					
Age	374	31.9	4.9	0.01	−0.10
Husband's age	370	33.4	5.4	0.03	−0.25
Body mass index (BMI)	370	21.1	3.1	1.29	1.82
Gestational week	374	11.0	1.6	0.4	2.08
PUQE-24					
Nausea	376	3.09	1.45	−0.37	−1.35
Vomiting	377	1.26	0.64	2.92	9.64
Richling	377	2.14	1.26	1.01	0.02
Total	376	6.50	2.71	0.53	−0.38
NVP-QOL					
NVP-QOL total	348	104.85	42.94	−0.04	−0.85
Daily fluid intake	357	904.34	391.95	0.94	−1.19
Predictive validity measures					
Changes fluid intake	379	4.00	1.44	−0.38	−0.51
Changes meal intake	377	3.24	1.62	0.49	−0.57
Urinary frequency	369	7.09	2.69	0.94	1.19
Emesis treatment	377	1.02	0.18	9.22	90.7
SDS					
SDS total	375	8.34	7.08	7.06	−0.15
PHQ-9					
Somatic	376	7.63	2.56	0.08	−1.00
Non-somatic	375	8.80	3.18	1.39	1.58
General	375	16.43	5.16	0.80	0.26
ISI					
ISI 1st factor	374	9.22	19.00	0.56	−0.29
ISI 2nd factor	368	5.91	13.00	0.60	−0.51

PUQE-24: Pregnancy-unique quantification of emesis and nausea; SDS: Sheehan disability scale; PHQ-9: Patient health questionnaure-9; Somatic: Somatic subscale score; Non-somatic: Non-somatic subscale score; General: Total score; ISI: Insomnia severity index; ISI 1st: ISI first factor score; ISI 2nd: ISI second factor score.

Pregnant women were distributed from the lowest (*i.e.*, 3) to the highest (*i.e.*, 15) PUQE-24 scores with low skewness and kurtosis (Table 1). The women's gestational weeks ranged from 4 to 19 weeks (Table S1), with a mean (SD) of 11.0 (1.6). Almost all other variables in women showed low skewness and kurtosis (Table 1).

The PUQE-24 scores were correlated with neither the women's age nor body mass index (BMI). However, it was slightly significantly ($p < 0.05$) correlated with gestational age ($r = -0.17$). As expected, the PUQE-24 scores were significantly correlated with the NVP-QOL scores ($r = 0.71$, $p < 0.001$), and reduced changes of fluid ($r = -0.22$, $p < 0.001$) and meal ($r = -0.34$, $p < 0.001$) intake. It was, however, not correlated with daily fluid intake, urinary frequency, or emesis treatment.

The PUQE-24 scores were also correlated with the scores of the SDS ($r = -0.39$, $p < 0.001$), PHQ-9 ($r = -0.36$, -0.38, -0.42, for Somatic, Non-somatic, and General factors respectively. $p < 0.001$) and ISI ($r = -0.29$ and -0.29 for the 1st and 2nd factors, respectively, $p < 0.001$) (Table S2).

Two-step cluster analysis yielded four clusters: Cluster 1 ($n = 69$ [18.4%]), Cluster 2 ($n = 153$ [40.7%]), Cluster 3 ($n = 85$ [22.6%]), and Cluster 4 ($n = 69$ [18.4%]). The silhouette coefficient was 0.4. Women in Cluster 1 scored higher than those in the other three groups in terms of nausea, vomiting, and retching (Table 2). Hence, we named this cluster Severe. Women belonging to Clusters 2 and 3 scored the same in terms of vomiting, and higher than those in Cluster 4 in nausea and retching. Those women belonging to Cluster 2 were scored higher than those belonging to Cluster 3 in terms of nausea and retching. Hence, we named these Clusters Moderate, and Mild, respectively. Women in Cluster 4 scored 1 (the lowest score) for nausea, vomiting, and retching. Hence, we named this Cluster No Symptoms.

Table 2. Mean scores of PUQE-24 by each cluster and the construct validity ($n = 376$).

	Cluster 1: severe nausea and vomiting	Cluster 2: moderate nausea and retching	Cluster 3: mild nausea and retching	Cluster 4: no symptoms	One-way ANOVA	Effect size	Tukey post hoc comparison
	$n = 69$ (18.4%)	$n = 153$ (40.7%)	$n = 85$ (22.6%)	$n = 69$ (18.4%)	$F(df)$	η^2	
PUQE-24							
Nausea	4.13	3.64	2.96	1.00	142.366 (3, 372)***	0.534	1 > 2 > 3 > 4
Vomiting	2.43	1.00	1.00	1.00	389.137 (3, 372)***	0.758	1 > 2 = 3 = 4
Retching	2.90	2.39	2.00	1.00	38.724 (3, 372)***	0.238	1 > 2 > 3 > 4
total	9.49	7.03	5.96	3.00	155.988 (3, 372)***	0.557	1 > 2 > 3 > 4
Demographic							
Age	31.26	32.76	31.52	31.92	2.738 (3, 368)*	0.022	1 = 2 = 3 = 4
Husband's age	32.91	34.41	32.63	32.88	2.694 (3, 364)*	0.022	1 = 2 = 3 = 4
Gestational weeks	10.80	10.77	11.02	11.70	6.016 (3, 372)***	0.046	1 = 2 = 3 < 4

Continued

Body mass index (BMI)	21.64	20.74	21.59	20.72	2.390 (3, 364) *NS*	0.019	
NVP-QOL							
Total	138.75	115.13	105.41	49.79	92.972 (3, 342)***	0.449	1 > 2 = 3 > 4
Predictive validity measures							
Daily fluid intake	806.45	864.09	982.32	1006.20	4.413 (3, 351)**	0.036	1 = 2 = 3 = 4
Changes fluid intake	3.45	3.88	4.34	4.42	7.592 (3, 372)***	0.058	1 = 2 = 3 = 4
Changes meal intake	2.43	3.15	3.43	4.06	13.321 (3, 371)***	0.097	1 < 2 = 3 = 4
Urinary frequency	6.51	7.23	7.55	6.88	2.170 (3, 363) *NS*	0.018	
Emesis treatment	1.04	1.03	1.01	1.00	0.801 (3, 371) *NS*	0.006	
SDS							
Total	10.91	9.05	8.25	4.31	11.739 (3, 369)***	0.087	1 = 2 = 3 > 4
PHQ-9							
Somatic	8.30	7.96	7.63	6.19	10.280 (3, 370)***	0.077	1 = 2 = 3 > 4
Non-somatic	10.07	9.14	8.51	7.12	11.747 (3, 369)***	0.087	1 = 2 = 3 > 4
General	18.38	17.10	16.14	13.31	13.772 (3, 372)***	0.101	1 = 2 = 3 > 4
ISI							
ISI 1st	10.22	9.38	9.34	7.73	7.413 (3, 368)***	0.057	1 = 2 = 3 > 4
ISI 2nd	6.35	6.05	6.04	5.02	3.874 (3, 362)**	0.031	1 = 2 = 3 = 4

*: $p < 0.05$; **: $p < 0.01$; ***: $p < 0.001$; *NS*: Not significant; PUQE-24: Pregnancy-unique quantification of emesis and nausea; SDS: Sheehan disability Scale; PHQ-9: Patient health questionnaure-9; Somatic: PHQ-9 somatic subscale score; Non-somatic: PHQ-9 non-somatic subscale score; General: PHQ-9 total score; ISI: Insomnia Severity Index; ISI 1st: ISI first factor score; ISI 2nd: ISI second factor score.

As expected, the women with No Symptoms were significantly older in terms of gestational age. Women in all the four Clusters did not differ in terms of their age or BMI. The NVP-QOL scores were in the order of Clusters, but not significantly different between the Moderate and Mild Clusters. The four Cluster women did not differ significantly in terms of daily fluid intake, changes in fluid intake or urinary frequency. Women belonging to Cluster 1 were characterised by greater reduction in meal intake. The four Cluster women did not differ in terms of emesis treatment. Clusters 1, 2, and 3 were scored significantly higher in social disability. Women in the Severe, Moderate, and Mild Cluster did not differ in terms of all PHQ-9 subscales and ISI scores, but they were significantly higher than the No Symptoms Cluster women except for the second subscale of the ISI.

ROC analyses were performed to determine the optimal cutoff points for the total PUQE-24. We performed ROC analyses for discrete No symptoms (Cluster 4) versus Mild, Moderate, and Severe clusters (Clusters 3 + 2 + 1); No symptoms

and Mild clusters (Clusters 4 + 3) versus Moderate and Severe cluster (Clusters 2 + 1), and No symptoms, Mild, and Moderate clusters (Clusters 4 + 3 + 2) versus Severe cluster (Cluster 1). The specificities, sensitivities, and positive and negative predictive values with a range of cutoff points were calculated. The best clinical cutoff point for No symptoms vs. Mild/Moderate/Severe was judged as 3/4 with perfect accuracy (**Table 3**). For No Symptoms/Mild vs. Moderate/Severe, the best clinical cutoff point was 6/7. The best clinical cutoff point for No Symptoms/Mild/Moderate vs. Severe was 7/8.

Table 3. PUQE-24 cutoff scores for four clusters.

Comparisons	Optimal cutoff points	Sensitivity	Specificity	Positive predictive value	Negative predictive value
No symptoms vs. mild, moderate, and severe	3/4	1.000	1.000	1.000	1.000
No symptoms and mild vs. moderate and severe	6/7	0.671	0.844	0.844	0.671
No symptoms, mild, and moderate vs. severe	7/8	0.783	0.779	0.783	0.779

4. Discussion

Among currently pregnant women, the scores of the PUQE-24 were widely distributed. The scores of the three items were normally distributed, except for vomiting which had high skewness and kurtosis. Among the present Japanese pregnant women, approximately 82% had emesis. The prevalence of emesis as well as distribution of emesis scores are in line with or virtually the same as those reported in other countries (although using different measures) such as England [1], Canada [52], China [53], and Finland [54].

The PUQE-24 scores were moderately correlated with those of the NVPQOL, another widely used measure of emesis, showing concurrent validity. Pregnant women with high PUQE-24 scores were more likely to experience reduced fluid and meal intakes during pregnancy, supporting criterion validity. The lack of a strong link between the experience of emesis treatment and current PUQE-24 scores was not unexpected because we distributed the questionnaire exclusively to outpatients. Even if they had previously received treatment for severe nausea and vomiting, they were asked about emesis just for the last 24 h when their emesis may have subsided. Further studies should include pregnant women currently undergoing treatment for emesis (such as those admitted). It is worth noting that there is no consensus about the definition of HG [4], and its treatment varies [55]-[58]. Clinicians and researchers may wish to administer the PUQE-24 for the women who are admitted for the hyperemesis gravidarum. As expected, pregnant women with high PUQE-24 scores were more likely to be socially disabled and have psychological symptoms, such as depression and insomnia. These findings were in line with previous literature (see Introduction). Clinicians should pay more

attention to symptoms and difficulties emesis women experience other than gastrointestinal ones. They should include reduced functioning in social, occupational, and private life. Pregnant women with emesis often suffer from lowered mood and occasional suicidal ideation. Sleep difficulties are another symptom pregnant women experience. More attention and intervention should be provided by perinatal health professionals.

Clinicians require a ranking inventory to categorise pregnant women into classes based on the severity of emesis. The clinical convention proposes four categories: None (PUQE-24, 3), Mild (PUQE-24, 4 - 6), Moderate (PUQE-24, 7 - 12), and Severe (PUQE-24, 13 - 15). Applying this convention to the present sample, however, only nine women (2%) were categorised as Severe. However, this approach was impractical. Our two-step cluster analysis with a fixed number of clusters at 4 was aimed at providing a more evidence-based categorisation of emesis cases. About a quarter of the women (Cluster 4) were free from symptoms of emesis. The remaining patients exhibited symptoms of emesis. This is consistent with the results of a previous epidemiological study on emesis. The three Clusters with emesis symptoms differed in that Cluster 1 women had both nausea and vomiting/retching, whereas Clusters 2 and 3 women mainly had nausea. Clusters 2 and 3 differed in terms of nausea and retching severity. ROC analysis revealed excellent or acceptable validity (sensitivity, specificity, and positive and negative predictive values) at cutoff points of 3/4, 6/7, and 7/8, respectively. Taking into consideration clinical utility, we think that the distinction between Moderate and Severe may be of little use. This is because 1) the first cluster women (Severe) are only 18% of the sample as compared to 41% of the second cluster women (Moderate), 2) extremely severe cases that needed hospitalisation may have been omitted from the study, and 3) women of Moderate Cluster scored in a very narrow range of only 7 on the PUQE-24.

Our study was not without drawbacks and limitations. Only about a quarter of the eligible pregnant women returned the questionnaire. This may be a resource of bias. Women with extremely severe emesis may not have declined from responding. We may have missed a population of very severe cases of emesis. However, pregnant women without emesis may not have been interested in participating in this questionnaire survey. For these possibilities, we should exercise caution in concluding to set a cutoff of the PUQE-24 scores distinguish clusters. We used a questionnaire survey with limited data on biological features (e.g., electrolytes). Psychological symptoms were rated using self-report measures. Therefore, clinician-rated interview data will provide detailed insights for future studies. Second, we collected data at a single time point. Our data may have been biased by the fact that emesis severity changes dramatically throughout the first trimester. The trajectory of emesis symptoms during pregnancy may cast more light on emesis research. It may be argued that the PUQE-24 covers emesis symptoms only for the previous 24 hours and that the time covered by the measure should be expanded to a week or two weeks. The latter recommendation, however, is subject to memory bias (e.g., women accurately remember yesterday's vomiting but forget

about the last week's one).

Despite these drawbacks, our study showed that the PUQE-24 is a valid and useful tool for measuring emesis in pregnant Japanese women. We recommend using a cutoff point of 6/7 for the detection of cases for treatment of emesis. It also highlights the multiple aspects of emesis, including gastrointestinal symptoms, psychosocial disability, and psychological maladjustment.

Ethics Approval and Consent to Participate

This study was approved by the Research Ethics Committees of Kitamura Institute of Mental Health Tokyo, Tokyo, Japan (no. 2015052301) and Kagoshima University (no. 170247). Study participants were anonymous. Therefore, all participants provided informed consent after understanding the study's rationale and procedures. The authors assert that all procedures contributing to this study complied with the ethical standards of the national and institutional committees on human experimentation and the Declaration of Helsinki of 1975, as revised in 2008.

Acknowledgements

We are grateful to all the anonymous participants.

Conflicts of Interest

The authors declare that they have no conflict of interests.

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Supplement

Table S1. Distributions and means of the scores of the PUQE and major variables.

Characteristics		Frequency	
PUQE-24 total score	Scores	*n*	%
Number of individuals by PUQE score	3	69	18.3
	4	29	7.7
	5	51	13.5
	6	54	14.3
	7	51	13.5
	8	34	9.0
	9	32	8.5
	10	19	5.0
	11	20	5.3
	12	8	2.1
	13	7	1.9
	14	1	0.3
	15	1	0.3
	Missing	2	0.5
	Total	376	100.0
Number of individuals with emesis (%) by gestational age	Weeks	*n*	%
	4 w	1/1	100.0
	8 w	14/15	93.3
	9 w	31/33	93.9
	10 w	95/107	88.8
	11 w	67/88	76.1
	12 w	61/76	80.3
	13 w	23/29	79.3
	14 w	12/21	57.1
	15 w	2/4	50.0
	16 w	0/1	0.0
	19 w	1/1	100.0
	Total	307/376	81.6
Employment status		*n*	%
	Employed	209	55.3
	Housewives	125	33.0
	Parental leave	23	6.1
	Students	3	0.8
	Others	13	3.5
	Missing	5	1.3
	Total	378	100.0

Continued

Change in fluid intake compared to pre-pregnancy		*n*	%
	1	24	6.3
	2	44	11.9
	3	51	13.5
	4	105	27.8
	5	102	27.0
	6	46	12.1
	7	6	1.6
	Total	378	100.0
Change in meal intake compared to pre-pregnancy		*n*	%
	1	53	14.0
	2	91	24.1
	3	83	22.0
	4	68	18.0
	5	38	10.1
	6	32	8.5
	7	12	3.2
	Missing	1	0.3
	Total	378	100.0
Outpatient visits for emesis		*n*	%
	0	373	98.7
	1	4	1.0
	2	0	0.0
	3	0	0.0
	4	1	0.3
	Total	378	100.0
		Mean (SD)	Median (min-max)
Weight loss compared to pre-pregnancy, Kg (n = 369)		−0.1 (2.1)	0.0 (−6.0 - 6.0)
Gestational age at start of NVP, wk (n = 305)		6.2 (1.5)	6.0 (1 - 11)

SD: Standard deviation; PUQE-24: 24 h pregnancy-unique quantification of emesis and nausea; NVP QOL: Nausea and vomiting of pregnancy quality of life; NVP: Nausea and vomiting of pregnancy; HG: Hyperemesis gravidarum.

Table S2. The severity ranking categories of the PUQE-24 according to original classification.

Characteristics	None (3) (n = 69)	Mild (4 - 6) (n = 134)	Moderate (7 - 12) (n = 164)	Severe (13 - 15) (n = 9)	PUQE-24 total score
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	r
PUQE-24					
Nausea	1.0 (0.0)	2.6 (0.7)	4.3 (0.9)	4.9 (0.3)	0.88***
Vomiting	1.0 (0.0)	1.1 (0.2)	1.4 (0.7)	3.8 (0.8)	0.58***
Retching	1.0 (0.0)	1.6 (0.6)	3.0 (1.2)	4.7 (0.7)	0.84***
Total	3.0 (0.0)	5.2 (0.8)	8.7 (1.6)	13.3 (0.7)	---
Predictive validity measures					
Daily fluid intake	1006.5 (419.3)	930.6 (363.2)	851.0 (387.1)	816.7 (563.5)	−0.16*
Changes fluid intake	4.4 (1.1)	4.2 (1.3)	3.7 (1.6)	3.0 (2.0)	−0.22***
Changes meal intake	4.1 (2.5)	3.4 (1.5)	2.8 (1.6)	1.8 (1.4)	−0.34***
Urinary frequency	6.9 (2.2)	7.2 (2.8)	7.2 (2.8)	5.6 (0.5)	−0.03 *NS*
Emesis treatment	1.0 (0.0)	1.03 (0.21)	1.01 (0.11)	1.22 (0.66)	0.07 *NS*
Demographic					
Age	31.1 (5.4)	31.8 (5.0)	32.4 (4.4)	29.3 (5.4)	0.07 NS
Gestational weeks	11.7 (1.6)	11.0 (1.5)	10.7 (1.6)	11.0 (1.7)	−0.17**
Body mass index (BMI)	20.7 (3.1)	21.0 (3.1)	21.3 (3.1)	21.0 (3.1)	0.04 NS
NVPQOL					
Total	49.8 (23.2)	100.2 (33.1)	128.4 (30.5)	171.0 (32.5)	0.71***
SDS					
Total	4.3 (5.3)	7.4 (6.8)	10.3 (7.1)	16.7 (5.5)	0.39***
PHQ-9					
Somatic	6.2 (2.4)	7.3 (2.5)	8.4 (2.4)	9.9 (2.5)	0.36***
Non-somatic	7.1 (1.7)	8.3 (2.8)	9.8 (3.5)	11.4 (4.4)	0.38***
General	13.3 (3.6)	15.5 (4.5)	18.2 (5.3)	21.3 (6.0)	0.42***
ISI					
ISI 1st	7.7 (2.8)	9.0 (3.0)	9.8 (3.3)	13.3 (3.2)	0.29***
ISI 2nd	5.0 (2.1)	5.5 (2.4)	6.5 (2.5)	7.8 (2.6)	0.29***

*: $p < 0.05$; **: $p < 0.01$; ***: $p < 0.001$; *NS*: Not significant; SD: Standard deviation; PUQE-24: 24 h pregnancy-unique quantification of emesis and nausea; NVPQOL: Nausea and vomiting of pregnancy quality of life.