



ABSTRACT

OBJECTIVES To validate the Premenstrual Symptoms Impact Survey (PMSIS™), a six-item self-assessment patient-reported outcomes instrument designed to evaluate impact of premenstrual symptoms on a woman's health-related quality of life.

METHODS The PMSIS and SF-12v2 Health Survey were administered via internet in two waves to females (18-45 Yrs) with some premenstrual complaints (e.g., irritability, depression, headache and abdominal bloating). Retrospective criteria from the American College of Obstetricians and Gynecologists and the DSM-IV-TR were used to categorize women into either Premenstrual Syndrome (PMS) or Premenstrual Dysphoric Disorder (PMDD) groups respectively. PMSIS responses were analyzed for internal consistency, reliability, convergent and discriminant/known-group validity, at each time point. Responses across times were analyzed for test-retest reliability.

RESULTS At Wave1 (N=1100) and Wave2 (N=770), 34.2% and 32.6% of participants were identified in the PMS group while 14.9% and 14.2% were identified in the PMDD group, respectively. The mean PMSIS scores at each wave were as follows: PMS groups (54.3, 52.0), Non-PMS groups (32.4, 28.3), PMDD groups (59.0, 55.0) and Non-PMDD groups (36.5, 32.8). The PMSIS showed good internal consistency at each time ($\alpha \geq 0.88$), and adequate test-retest reliability across times (intra-class correlation: 0.74). PMSIS scores correlated significantly ($p < 0.001$) with SF-12 Physical Component Summary (PCS) and Mental Component Summary (MCS) scores. At each time, PMSIS scores discriminated well across presence/absence of PMS and PMDD (all F's > 100, all ps < 0.001), and between low/medium/high PCS and MCS groups (all F's > 24, ps < 0.001), indicating known-group discriminant validity. Receiver operating characteristics analyses showed satisfactory values for areas under the curve (≥ 0.78) in detecting women with PMS and/or PMDD at each time.

CONCLUSIONS This study demonstrates that the PMSIS has good internal consistency, test-retest reliability, and convergent and discriminant validity, making the PMSIS a viable option for identifying and assessing premenstrual problems.

BACKGROUND

Premenstrual disorders, including both premenstrual syndrome (PMS) and premenstrual dysphoric disorder (PMDD), can interfere with a woman's interpersonal relationships, social activities, work absenteeism and productivity, and health-related quality of life (HRQOL).¹⁻⁴ The majority of the existing instruments document the presence and severity of premenstrual symptoms, but not associated HRQOL impairment. A psychometrically validated reliable and brief instrument – the Premenstrual Symptoms Impact Survey (PMSIS™) – was recently developed to evaluate the impact of those symptoms on women's HRQOL.⁵

The PMSIS includes six items with six response choices for each item. The PMSIS is intended to provide an easy assessment tool for women and clinicians to evaluate and monitor the impact and treatment effectiveness of premenstrual disorders on HRQOL.

OBJECTIVES

To further validate the PMSIS among women with and without premenstrual disorders (either PMS or PMDD), by assessing: 1) internal consistency and test-retest reliability; 2) convergent and discriminant validity; and 3) accuracy in classifying women into with and without premenstrual disorders.

METHODOLOGY

Data Sources

- Data were collected via internet from eligible participants of the U.S. female members of the Zoomerang panel
- Inclusion criteria:** 18 – 45 years old; regular menstrual cycles for the past three months; at least one of the premenstrual symptoms from the 2000 ACOG diagnostic criteria for PMS⁶
- Exclusion criteria:** Pregnant, nursing, or irregular menstrual cycles; use of anti-anxiety, antidepressant, or hormone replacement medications within 3-months prior to study; diagnosed with depression, anxiety disorder, eating disorder, or drug and/or alcohol disorder within 2 years prior to study
- Survey instruments:**
 - PMSIS (range from 0-100, with a higher score indicating worse impact on HRQOL)⁵
 - SF-12v2® Health Survey⁷
 - Work Limitations Questionnaire (WLQ)⁸
 - Work Productivity and Activity Impairment: Specific Health Problem (WPAI:SHP)⁹
 - Sexual Function Questionnaire – Desire Domain (SFQ-D)¹⁰
- Premenstrual disorder classification criteria**
 - Retrospective component of the ACOG criteria⁶ for PMS diagnosis
 - Retrospective component of the DSM-IV-TR¹¹ for PMDD diagnosis

Table 1: Comparison of Means (SDs) for PMSIS Scores by Group and Time-Point

Group	Level	Time 1				Time 2			
		N (%)	Mean	SD	F	N (%)	Mean	SD	F
PMS	Present	377 (34.3)	54.3	17.4	331.1***	251 (32.6)	52.0	18.2	259.7***
	Absent	723 (65.7)	32.4	19.8		519 (67.4)	28.3	19.6	
PMDD	Present	164 (14.9)	59.0	15.6	174.0***	109 (14.2)	55.0	14.9	107.2***
	Absent	936 (85.1)	36.5	20.8		661 (85.8)	32.8	21.6	
Full Sample		1100	39.9	21.7		770	36.0	22.1	

*** indicates significance at $p < .001$

Table 2: Reliability of PMSIS Scores by Group and Time-Point

Group	Time 1		Time 2		Intraclass correlation across times
	Cronbach's alpha	Average inter-item correlation	Cronbach's alpha	Average inter-item correlation	
PMS	0.80	0.40	0.84	0.47	0.59
PMDD	0.75	0.35	0.78	0.39	0.48
Full sample	0.88	0.54	0.90	0.60	0.74

Table 3: Convergent Validity: Correlations among PMSIS Scores and Criterion Variables

Criterion Measure	Time 1	Time 2
PCS-12	-0.21***	-0.24***
MCS-12	-0.45***	-0.56***
PMS ^a	0.48***	0.50***
PMDD ^a	0.37***	0.35***
Mean correlation^b	0.38	0.42

^a Computed using point biserial correlation (absence = 0, presence = 1)

^b Computed using Fisher's z transformation of absolute values of correlations to reflect magnitude only

*** indicates significance at $p < .001$

Table 4: Classification accuracy: Overall Area under the Curve for PMS and PMDD Groups

Group	AUR: Time 1	AUR: Time 2
PMS	.794***	0.811***
PMDD	.799***	0.808***

AUR: Area under ROC curve

*** indicates $p < .001$

RESULTS

Comparison of PMSIS scores by group and time-point (Table 1)

- Chi-square analyses showed no difference in the relative frequency of PMS or PMDD group classification across time-point ($\chi^2 < 1$)
- T-tests indicated that PMSIS scores were higher at Time 2 than at Time 1 for both groups as well as the total sample (all ps < .01)
- Known-groups discriminant validity: PMS/PMDD-present groups had significantly higher PMSIS scores than non-PMS/non-PMDD groups, indicating discrimination by the PMSIS across known groups

Reliability (Table 2)

- For the total sample at each time-point, all reliability coefficients are above conventional thresholds (0.7 for Cronbach's alpha, 0.4 for inter-item correlations, 0.7 for intraclass correlation), indicating adequate reliability of the PMSIS

Convergent validity (Table 3)

- All correlations were significant and in the hypothesized direction, indicating statistical convergence between PMSIS and other criterion variables.

Classification accuracy (Table 4)

- For both groups at both times, AUR is significantly greater than 0.5, and approaches/exceeds 0.8, indicating that the PMSIS scale provides acceptable accuracy in classifying patients for having PMS or PMDD.

LIMITATIONS

This is a patient-reported outcome study based on an online internet survey.

Only retrospective component of diagnostic criteria were used for determining whether women were likely to have PMS or PMDD.

Symptom checklist was used for premenstrual symptom complaints.

Clinical application of the survey is warranted.

CONCLUSIONS

PMSIS is a reliable and valid tool for evaluating the HRQOL impact due to premenstrual disorders.

PMSIS can be used as a self-evaluation tool for women suffering from premenstrual disorders.

A report on PMSIS results can help initiating the dialogue between women suffering from premenstrual disorders and clinicians, and thus for women to obtain treatment to control premenstrual symptoms.

PMSIS can be considered for longitudinal monitoring in the change of health-related quality of life for women on treatment for premenstrual disorders.

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