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Research Article

Development and Validation of the Menstrual Health Outcome Questionnaire to Evaluate QoL among Women during Menstrual Cycle

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ABSTRACT

Menstruation is a physiological process experienced by adolescent girls and women. Menstruation and premenstrual symptoms affect the Quality of Life. Different scales are available to measure QoL for different gynecological problems, but none are available for QoL during menstruation. WHO defines QoL as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a multidimensional concept that includes physical, mental, emotional and social functioning domains. It goes beyond direct measure of population health, life expectancy and causes of death and focuses on the impact of health status on quality of life. To develop a comprehensive instrument to assess the health-related QoL among women during menstruation. The creation of a scale to assess QoL during the menstrual cycle is indeed a significant endeavor. Menstrual health outcomes questionnaire contains 35 questions from different domains. After getting ethical approval pilot and pivotal study were conducted. Adolescents were randomly recruited in the study. Data was captured and entered in SPSS version 20. Principle factor analysis was determined to find construct validity among independent and dependent variables. Man-Whitney U-test was determined. A questionnaire has Cronbach's alpha 0.796, determined 35 questions. The intraclass correlation coefficient was found 0.786. KMO and Bartlett's test was found 0.820 with high significance ($p = 0.000$). The menstrual health outcome questionnaire has been established as a valid and reliable tool for assessing the QoL among women during menstruation.

INTRODUCTION

Menstruation is a physiological process experienced by adolescent girls and women. Menstruation can have a significant impact on the lives of girls and women, and it's unfortunate that it remains a taboo in many parts of India. Developing a QoL scale for menstruation could indeed help assess the unique challenges and experiences related to this natural process and provide valuable insights for healthcare and policy. WHO's definition of QoL emphasizes the importance of considering an individual's cultural and societal context when assessing their well-being, which is particularly relevant in the case of menstruation. It is a multidimensional concept that encompasses various aspects of physical, mental, emotional, and social well-

being. The cultural and societal context in India, where there can be a reluctance to openly discuss women's health issues, including those related to the reproductive system, can indeed impact women's ability to express their views and seek proper healthcare.

Promoting awareness, education, and open dialogues about these topics can help empower women to take charge of their reproductive health and improve their overall quality of life. Breaking taboos and fostering a more inclusive and informed environment is essential for addressing these challenges effectively.

Some studies conducted in different parts of India suggested a higher prevalence of premenstrual symptoms among adolescent girls.^[1] Dysmenorrhoea is considered

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as physical symptom during menstruation and it was not only affects girls' physical health but also affects their daily living and social activities. One study performed among Chinese adolescent girls in Hong Kong was reveals the majority of the participants had dysmenorrhea during menstruation which limits their routine activities.^[2] Premenstrual symptoms can be varied in physical and psychological type. Many of them can be felt by girls during the menstrual cycle like headache, backache, vomiting, mood swings, anxiety, cravings for specific food etc. Physical symptoms limit routine living practice and psychological symptoms affect the mental health of the girls.

As per the literature search, many studies were conducted in India and other countries regarding the assessment of the quality of life of adolescents respective to the various menstrual comorbidities. Hence, none scale is available specifically for the changes or morbidities taking place before, during and after menstruation which has tendency to deviate from quality of life (QoL).^[4-6] The lack of a specific scale to assess the changes and comorbidities related to menstruation is indeed a gap in the field of healthcare and QoL assessment. With the age of menarche occurring earlier in some cases, it's important to pay attention to the physical and psychological symptoms experienced by adolescents, which can impact their overall well-being. Depression, hopelessness, mood swings, get easy frustration are common premenstrual syndrome (PMS) which found to be higher in adolescents.^[7-11] Depression, mood swings, and other symptoms associated with PMS can be particularly challenging for adolescents. Designing a specialized scale to measure specific factors can enhance our understanding of the impact on quality of life, allowing for tailored interventions and support. Developing such a scale for the menstrual cycle is a substantial undertaking. It's crucial to incorporate diverse perspectives from women in different menstrual phases for comprehensive insights. The creation of a scale to assess the quality of life during the menstrual cycle is indeed a significant endeavor.

MATERIALS AND METHODS

Objectives

The aim of this study was to develop a comprehensive instrument to assess the health-related quality of life among women during menstruation.

Inclusion Criteria

Menstruating girls studying in selected schools and colleges have age of more than 13 years.

Girls willing to sign ICF.

Exclusion Criteria

Girls are not willing to sign ICF.

Girls did not attain her first menarche.

Study Design

Observational, prospective and cross-sectional study.

Menstrual Health Outcomes Questionnaire development

The authors prepared menstrual health outcomes questionnaire. A literature search was done to understand different QoL scales available for different gynecological problems. No QoL scale is available which can be used during the menstrual cycle. Few questions were prepared in line with quality of life scale SF-36^[12] & SF-12.^[13] The questionnaire consists of 35 questions of different QoL domains like physical, economic, social, emotional, psychological, life satisfaction. The physical domain has 6 questions about routine household, exercise and traveling activities. The economic domain has 3 questions regarding economic criteria. Two questions of social domain covered social activities like outing and social gatherings. Six questions about relationships and concentration in routine activities were asked about the emotional domain. A total 14 questions belonged to psychological and life satisfaction domains. Last question was about to rate health status before, during and after menstruation. Expert's opinion validated questionnaire. The questionnaire was translated in the vulnerable language before being administered to subjects.

Ethical Approval

Prepared documents like ICF, CRF and protocol along with the prepared menstrual health outcomes questionnaire was submitted to Sarvajani Clinical Research Ethics Committee to obtain ethical approval before data collection. This study was conducted in accordance with GCP and new drug clinical trial rule-2019.

Pilot Testing

Pilot study was performed to validate the prepared questionnaire. A total of 65 school and 102 college girl respondents were randomly enrolled to complete pilot study. After collecting the data of pilot study, data were analyzed using IBM SPSS version 20.

Content and Construct Validity

Cronbach's alpha was determined to check the constructed validity among the items. Table 1 represents individual Cronbach's alpha of the separate domains. Table 2 showed an intraclass correlation coefficient of 0.786, suggesting good reliability at 95% confidence interval. Table 3 represents the results of item total statistics suggesting the Cronbach's alpha if any item is deleted. Principle factor analysis was determined to find the construct validity of the developed questionnaire. The results of principle factor analysis was represented using scree plot and KMO measure.

Table 1: Cronbach's alpha for each domain during pilot study

Domains	Total no. of item	Number of questions	Mean $\pm$ SD	Range	Cronbach alpha
Overall health	07	4	9.69 $\pm$ 2.29	4–17	0.597
Physical		6	10.71 $\pm$ 2.44	6–19	0.598
Economical		3	7.09 $\pm$ 2.07	3–9	0.856
Social		2	6.18 $\pm$ 1.36	3–9	0.769
Emotional		6	2.64 $\pm$ 0.85	2–4	0.570
Psychological		7	12.08 $\pm$ 3.94	7–21	0.894
Overall satisfaction		7	16.94 $\pm$ 4.12	7–21	0.919
Overall		35	73.02 $\pm$ 9.12	40–98	0.796

Pivotal Study

After getting the questionnaire's acceptable Cronbach's alpha and intraclass correlation coefficient, a pivotal study was started. Personal interview was taken to fill the questionnaire, girls from school & college were selected randomly. Collected data were entered and analyzed to compare both age groups. The man-Whitney U test was determined to study significant differences among age groups. *p-value* >0.05 is considered non-significant, *p-value* $\leq$ 0.05 is considered significant, *p-value* <0.01 is considered very significant and *p-value* <0.001 is considered highly significant.

RESULTS

In this prospective cross-sectional study, 481 girls were recruited. Among them, 338 girls were from a school, aged 13 to 17 years, with a mean age of 15.78 $\pm$ 1.15 years. Additionally, 143 girls were from a college, aged 17 to 24 years, with a mean age of 20.51 $\pm$ 3.56 years as mentioned in Table 4.

Table 1 shows the Cronbach's alpha values obtained for each domain in the questionnaire. The questionnaire comprises a total of 35 questions, with an overall Cronbach's alpha value of 0.796, indicating its reliability. The questionnaire is divided into 7 domains, each with a different number of questions and corresponding Cronbach's alpha values. Overall health domain: 4 questions with a Cronbach's alpha of 0.597. Physical Domain: 6 questions with a Cronbach's alpha of 0.598. Emotional Domain: 6 questions with a Cronbach's alpha of 0.570. Psychological Domain: 7 questions with a high Cronbach's alpha value of 0.894. Satisfaction Domain: 7 questions with a very high Cronbach's alpha value of 0.919. Economic Domain: 3 questions with a Cronbach's alpha of 0.856. Social Domain: 2 questions with a Cronbach's alpha of 0.769. These Cronbach's alpha values suggest that the questionnaire has a reliable quality of life measurement across its various domains, with the overall score meeting an acceptable standard of 0.796.

Table 3 provides a comprehensive overview of total item statistics for a questionnaire used to assess quality of life across seven distinct domains. This table includes

key statistics such as the mean, variance, scale-related metrics, corrected item-total correlations, and Cronbach's alpha values when each item is deleted from the scale. These insights offer a detailed understanding of the questionnaire's performance and the contribution of individual items to the overall assessment.

Table 2 presents the intraclass correlation coefficients, with a single measure value of 0.0095 and an average measure value of 0.786. These values indicate that the developed questionnaire exhibits an acceptable level of reliability.

Table 5 provides a comparison of the quality of life between school and college students. The Mann-Whitney U-test was employed for this analysis, with *p-values* greater than 0.05 considered non-significant. Notably, sports activity and the amount of time spent on work were found to be significantly different from each other. Traveling activity showed a highly significant *p-value* of 0.003. In the economic domain, each question was found to be significant between the groups, particularly with regard to having enough money to meet their needs, which exhibited a highly significant value. However, the social domain did not show significance between the groups. Concentration in routine work or study displayed a highly significant *p-value* in the emotional domain.

Additionally, five questions from the psychological domain were analyzed, including tension or anxiety, depression, lack of energy, nervousness, and guilt. Mood swings showed a highly significant *p-value*. Economic status, ability to maintain a routine fashion and physical health were found to be significant between the groups. Furthermore, overall health was found to be highly significant when asked about the girl's health rate before, during and after menstruation.

In the analysis to assess the construct validity of the questionnaire, a principal factor analysis was conducted.

Table 2: Intraclass correlation coefficient

	Intraclass correlation	95% Confidence interval	
		Lower bound	Upper bound
Single measures	0.095	0.076	0.119
Average measures	0.786	0.743	0.826



Table 3: Total item statistics of a questionnaire

<i>Questions</i>	<i>Scale mean if item deleted</i>	<i>Scale variance if item deleted</i>	<i>Corrected item-total correlation</i>	<i>Cronbach's alpha if items deleted</i>
Physical domain				
Routine activities	71.30	77.183	0.252	0.764
Routine exercise activities	71.95	78.763	0.115	0.770
Sports activities	71.72	77.196	0.225	0.765
Travelling activities	71.55	78.48	0.140	0.769
Cut down the amount of time you spent on work	72.23	79.521	0.148	0.768
Accomplished less than you would like	72.29	79.56	0.151	0.768
Economical domain				
Enough money to meet expenses	71.17	76.27	0.348	0.760
Money for leisure activities	71.23	75.72	0.383	0.758
Living expenditure	71.20	76.305	0.340	0.760
Social Domain				
Outings	71.59	77.64	0.208	0.766
Social gatherings	71.52	77.810	0.208	0.766
Emotional domain				
Concentrated properly in household work/study	71.14	76.205	0.354	0.760
Personal Relationship	71.24	76.460	0.302	0.762
Relationship with family and friends	71.18	76.357	0.347	0.760
Support from family and friends	71.20	75.83	0.391	0.758
Cut down the amount of time you spent on work	72.20	79.564	0.140	0.768
Accomplished less than you would like	72.28	80.002	0.096	0.796
Psychological domain				
Mood swings	71.83	77.516	0.211	0.766
Anxiety or tension	72.06	77.67	0.205	0.766
Depression or hopelessness	72.02	78.15	0.172	0.768
Nervousness	72.15	78.48	0.153	0.768
Lack of energy	71.92	78.52	0.132	0.770
Get frustrated easily	71.96	78.846	0.116	0.770
Feel tiredness	71.60	77.434	0.254	0.764
Life satisfaction				
Physical health	71.41	75.188	0.400	0.757
Ability to function in daily life	71.38	73.86	0.515	0.752
Enjoyment in life	71.25	74.63	0.484	0.754
Overall sense of well being	71.34	74.512	0.501	0.753
Economic status	71.41	74.28	0.471	0.754
Daily life feeling	71.37	73.649	0.484	0.753
Sleep satisfaction	71.34	74.697	0.446	0.755
Health				
Before menstruation	70.59	75.567	0.168	0.774
During menstruation	71.01	78.844	0.084	0.773
After menstruation	70.50	76.032	0.182	0.771

Table 4: Age groupwise distribution of data

No	Age group	Age range (years)	Mean $\pm$ SD (year)
1	School	13–17	15.78 $\pm$ 1.15
2	College	17–24	20.51 $\pm$ 3.56

This involved determining the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy, a widely used diagnostic measure. Typically, a KMO measure of 0.50 or lower is considered unacceptable, while a value greater than 0.80 is deemed acceptable for the questionnaire.

In this study, the KMO measure was found to be 0.820, which falls within the acceptable range. Moreover, this result was highly significant, with a *p-value* of 0.000, indicating the robustness of the analysis (Table 6).

Table 5: Comparison of QoL among school and college girls

Domain	Questions	Mean $\pm$ SD (School Girls)	Mean $\pm$ SD (College Girls)	<i>p-value</i>
Physical	Routine activities	2.38 $\pm$ 0.716	2.42 $\pm$ 0.72	0.497
	Routine exercise activities	1.50 $\pm$ 0.67	1.62 $\pm$ 0.76	0.107
	Sports activities	1.92 $\pm$ 0.76	1.74 $\pm$ 0.81	0.026*
	Travelling activities	1.89 $\pm$ 0.73	2.14 $\pm$ 0.80	0.003**
	Cut down the amount of time you spent on work	1.29 $\pm$ 0.45	1.40 $\pm$ 0.49	0.032*
	Accomplished less than you would like	1.25 $\pm$ 0.43	1.36 $\pm$ 0.48	0.023*
Economical	Enough money to meet expenses	2.52 $\pm$ 0.77	2.36 $\pm$ 0.78	0.000***
	Money for leisure activities	2.41 $\pm$ 0.77	2.30 $\pm$ 0.76	0.016**
	Living expenditure	2.49 $\pm$ 0.78	2.41 $\pm$ 0.77	0.029*
Social	Outings	1.85 $\pm$ 0.69	1.95 $\pm$ 0.71	0.092
	Social gatherings	1.97 $\pm$ 0.67	1.91 $\pm$ 0.71	0.515
Emotional	Concentrated properly in household work/study	2.48 $\pm$ 0.73	2.32 $\pm$ 0.72	0.000***
	Personal Relationship	2.53 $\pm$ 0.77	2.51 $\pm$ 0.70	0.127
	Relationship with family and friends	2.54 $\pm$ 0.76	2.61 $\pm$ 0.64	0.716
	Support from family and friends	2.50 $\pm$ 0.77	2.53 $\pm$ 0.68	0.442
	Cut down the amount of time you spent on work	1.35 $\pm$ 0.47	1.33 $\pm$ 0.47	0.404
	Accomplished less than you would like	1.29 $\pm$ 0.45	1.30 $\pm$ 0.46	0.949
Psychological	Mood swings	1.66 $\pm$ 0.69	1.81 $\pm$ 0.68	0.021*
	Anxiety or tension	1.46 $\pm$ 0.66	1.74 $\pm$ 0.70	0.000***
	Depression or hopelessness	1.44 $\pm$ 0.62	1.70 $\pm$ 0.73	0.000***
	Nervousness	1.33 $\pm$ 0.61	1.51 $\pm$ 0.68	0.000***
	Lack of energy	1.46 $\pm$ 0.66	1.76 $\pm$ 0.73	0.000***
	Get frustrated easily	1.46 $\pm$ 0.65	1.63 $\pm$ 0.70	0.003***
	Feel tiredness	1.92 $\pm$ 0.68	1.90 $\pm$ 0.71	0.786
Life satisfaction	Physical health	2.14 $\pm$ 0.81	2.35 $\pm$ 0.69	0.019*
	Ability to function in daily life	2.22 $\pm$ 0.80	2.43 $\pm$ 0.69	0.034*
	Enjoyment in life	2.46 $\pm$ 0.74	2.48 $\pm$ 0.69	0.869
	Overall sense of well being	2.30 $\pm$ 0.76	2.37 $\pm$ 0.70	0.541
	Economic status	2.22 $\pm$ 0.83	2.44 $\pm$ 0.68	0.014*
	Daily life feeling	2.30 $\pm$ 0.80	2.39 $\pm$ 0.70	0.491
Health	Sleep satisfaction	2.36 $\pm$ 0.74	2.45 $\pm$ 0.69	0.303
	Before menstruation	3.53 $\pm$ 1.03	3.70 $\pm$ 0.96	0.000***
	During menstruation	2.64 $\pm$ 0.83	3.20 $\pm$ 0.87	0.000***
	After menstruation	3.50 $\pm$ 0.95	3.74 $\pm$ 0.91	0.000***

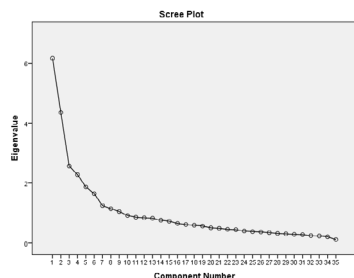
*Significant, **very significant, ***highly significant



Table 6: Results of KMO and Bartlett's test

KMO and Bartlett's test		
Kaiser-Meyer-Olkin measure of sampling adequacy		.820
Bartlett's test of Sphericity	Approx. Chi-square	4912.567
	df	595
	Sig.	.000***

***highly significant

**Fig. 1:** Scree plot

The scree plot displayed above represents a graph depicting the total number of components versus the derived eigenvalues as showed in Fig. 1. This analysis suggests that a total of 35 components can be effectively grouped into 9 distinct factors using principal factor analysis. This determination is based on the initial 9 factors exhibiting eigenvalues exceeding 1, indicating their significance in the analysis.

DISCUSSION

Developing and validating a questionnaire to evaluate women's QoL during their menstrual cycle is an important contribution, especially given the lack of specific tools for assessing QoL during this period. Existing questionnaires tend to focus on gynecological problems like: Uterine fibroid (UFS-QoL),^[14] PCOS (PCOSQoL),^[15] cervical cancer (EORTC QoL-30,^[16] QLQ-C30^[17]), endometriosis (EHP-30,^[18] EHP-5),^[19] prolapsed organ (P-QoL^[20]) and menopause specific MENQoL^[21] etc. As menstruation has hormonal fluctuations can indeed impact daily activities, so a dedicated scale for measuring QoL during menstruation is valuable.

Menstrual health outcome questionnaire received positive feedback on its content validation from experts. Additionally, including domains that impact quality of life as outlined in the SF-12^[13] and SF-36,^[13] which are commonly used for assessing general health, suggests that this questionnaire comprehensively addresses various aspects of women's well-being during the menstrual cycle. This could make it a robust tool for evaluating the QoL of women during this specific period.

The strong reliability and validity of the menstrual health outcome questionnaire, as evidenced by moderate to high Cronbach's alpha values ranging from 0.59 to 0.91, is a positive indicator. A researcher gave a positive rating for internal consistency when Cronbach's alpha was found >

0.70.^[22] Furthermore, an intraclass correlation coefficient of 0.786 suggests that the questionnaire can effectively measure the quality of life among menstruating women, reinforcing its utility as a valuable assessment tool in line with other studies conducted.^[22-26]

Each domain in the questionnaire has its own set of questions with multiple response options, allowing participants to provide their justifications based on their experiences during their menstrual cycle like definitely, sometimes and not at all. The mean $\pm$ SD for each question was determined among the age groups as shown in Table 5, which can provide insights into how women of different age ranges perceive and experience the effects of menstruation on their quality of life. This data can be valuable for further research and understanding the nuances of this aspect of women's health.

This study determined statistical tests to find significant differences for all the questions among the groups. Out of all, some were statistically significant from the physical health domain sports activities (0.026), cut down the amount of time spent (0.032), felt accomplished less than would like (0.023). Economic domains have 0.029 as *p-value* asked about meeting living expenses. Psychological symptoms were asked to respondents whether those symptoms affect QoL during menstruation, and their mood swings (0.021) were statistically significant. Some questions regarding overall life satisfaction were asked out of all, satisfaction from physical health (0.019), ability to function daily life (0.034) and satisfied from economic status (0.014) found statistically significant. These findings can be essential in understanding how different factors impact the quality of life during menstruation, providing valuable insights for future research and interventions to improve women's well-being during this time.

The high statistical significance found in questions from various domains, such as limitation in traveling activities (0.003), enough money to meet routine living expenses (0.000), money for leisure activities (0.016) and properly concentrated in household work/study (0.000). Some psychological symptoms were had high significance as follows: anxiety or tension (0.000), depression (0.000), nervousness (0.000), lack of energy (0.000) and get frustrated easily (0.003) from psychological domain suggests that these factors have a substantial impact on the quality of life during menstruation. Understanding these significant differences can help tailor interventions and support to address specific challenges women may face during their menstrual cycles, ultimately improving their well-being.

The high statistical significance with a *p-value* of 0.000 for the question regarding health before, during, and after menstruation suggests that how women perceive their health in these different phases of their menstrual cycle is a crucial aspect of the study. This finding underscores the importance of considering the variations in health and well-being across these different timeframes and how it can significantly impact their overall quality of life.

The principle factor analysis with various criteria, including commonalities, total variance, scree plot, component matrix, rotated component matrix, and component transformation matrix, is a comprehensive approach to understanding the underlying factors suggesting an acceptable value of KMO. The fact that each variable has different correlations with the nine groups suggests that these variables may be multidimensional or influenced by multiple factors. When a variable exhibits both positive and negative correlations with different factors, it implies that it's not exclusively related to one underlying dimension, and its impact may vary in different contexts. This complexity can provide valuable insights into the relationships and nuances within data.

CONCLUSION

The menstrual health outcome questionnaire has been established as a valid and reliable tool for assessing the quality of life among women during menstruation. The fact that it can be applied to different age groups makes it a versatile instrument for researchers and healthcare professionals to understand and address the specific needs and experiences of women across various age ranges during their menstrual cycles. This could have important implications for improving women's health and well-being.

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