

Original Research



Health-related quality of life questionnaire for women with polycystic ovary syndrome: a Sinhala translation and validation study

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DOI: <https://doi.org/10.4038/jccpsl.v27i2.8335>

Received on 13 May 2020

Accepted on 24 April 2021

Abstract

Introduction: Polycystic ovary syndrome (PCOS) has a negative impact on the health-related quality of life (HRQoL) of affected women. There are no studies conducted on HRQoL of women with PCOS in Sri Lanka, partly due to non-availability of a disease-specific validated tool.

Objectives: To translate and evaluate the validity and reliability of the modified polycystic ovary syndrome health-related quality of life questionnaire (M-PCOSQ) among Sri Lankan women with PCOS

Methods: The M-PCOSQ was translated into Sinhala language and content and consensual validity was assessed using modified Delphi process. The Short Form Health Survey (SF-36) Sinhala version and translated M-PCOSQ were completed by 94 participants attending three different clinics at a maternity hospital in Sri Lanka. Convergent validity was measured using SF-36 while divergent validity was not measured due to the absence of a suitable tool. Ethical issues were adequately addressed. Retest was done in 10% of the sample two weeks later.

Results: With the modified Delphi process, items 4, 10 and 27 of M-PCOSQ Sinhala version were stated as positive statements and scoring changed accordingly. The mean age of the sample was 27.13 years and the majority (77.1% had no children). All six domains of M-PCOSQ had high intra-class correlation coefficients ranging from 0.97 to 0.99 demonstrating excellent test-retest reliability. Cronbach's alpha was 0.67 or more for four of the six domains indicating satisfactory internal consistency. Construct validity was observed by the high correlation between emotion subscale of M-PCOSQ and emotional well-being scale of SF-36 ($r=0.63$; $p<0.01$).

Conclusions and Recommendations: M-PCOSQ-Sinhala version is a valid and reliable tool to measure HRQoL of PCOS women.

Keywords: *health-related quality of life, M-PCOSQ, reliability, Sri Lanka, validity*

Introduction

Polycystic ovary syndrome (PCOS), which is characterized by oligomenorrhoea/amenorrhoea, anovulatory infertility, hirsutism, obesity and polycystic ovaries on ultrasound scanning, affects approximately 6.3% Sri Lankan women in the age range of 15-39 years (1). These symptoms have adverse psycho-social effects across a vast arena of an affected woman's life, including family dynamics, professional and leisure activities and physical fitness resulting in significantly compromised health-related quality of life (HRQoL) (2-3). Throughout the years, numerous generic HRQoL questionnaires have been used in PCOS research. Development and validation of the Polycystic Ovary Syndrome Questionnaire (PCOSQ) by Cronin and colleagues led to immense progress in HRQoL research in PCOS as it captures disease-specific issues such as infertility, hirsutism, etc. (4-5). This has been translated into several languages such as German, Swedish and Chinese (6-9). Furthermore, Barnard and colleagues modified the PCOSQ with the addition of acne subscale (10). This modified PCOSQ (M-PCOSQ) has been translated into the Persian language (11-12). Several studies conducted in the USA, UK, Canada, Germany, Iran, Australia and Sweden with these instruments have reported the impact of PCOS on HRQoL (13). Nevertheless, data published in the South Asian context is not robust enough to draw definitive conclusions.

Kumarapeli and colleagues in 2010 (14) reported that there is a 'culture of silence' among Sri Lankan women as only 55% of PCOS women have sought medical assistance to manage their symptoms although 32.9% have experienced psychological distress because of the illness. Nevertheless, that study had used WHO QOL-BREF which is a generic instrument and has highlighted the need for a PCOS specific questionnaire for in-depth analysis of HRQoL of Sri Lankan women with PCOS. Therefore, translation and validation of M-PCOSQ contribute to the discipline by making available the first PCOS specific health-related quality of life questionnaire in Sri Lanka. Thus, the validation of M-PCOSQ helps researchers and clinicians to

understand the symptoms of PCOS contributing to diminish HRQoL and bridge the gap between medical and psychological management of PCOS. Objective of the study was to translate and validate a Sinhala version of the M-PCOSQ by evaluating its content, consensual and construct validity, internal consistency and test-retest reliability. This will enhance our understanding about how Sri Lankan women perceive the burden caused by PCOS and the major contributing symptoms towards low HRQoL, as many cross-cultural studies have shown that symptoms that caused diminished HRQoL and psychological distress varies among different ethnicities (15-16).

Method

Translation

Two bilingual translators (i.e., fluent in both English and Sinhala languages) independently translated the item content, response options and instructions into the Sinhala language from English. The two forward translations were combined to generate a provisional version after discussing with a consultant community physician and the translators. Another bilingual translator who was blinded to the original version, back-translated the provisional Sinhala version of M-PCOSQ into English language. The final English version was compared with the original questionnaire by a bilingual expert to examine for discrepancies.

Content and consensual validity

Modified Delphi process was used to assess content and consensual validity of the M-PCOSQ. This technique is an adaptation of the traditional Delphi method in which the panel of experts will contribute their input in terms of discussion, feedback and revisions without working face to face (17). The modified Delphi technique used in the present study utilized individual e-mails to gather expert opinions during the translation process. Face validity, consensual validity and content validity were assessed by judgment. The expert panel consisted of a consultant psychiatrist, a consultant endocrinologist, a consultant community physician and a psychologist.

The translated version of the questionnaire with 30 items was mailed to the panel of experts to rate the items of the scale based on three given criteria, namely cultural relevance, importance of the item to assess the sub-scale and translation. A Likert scale ranging from 0 (total disagreement) to 10 (total agreement) was used to assess the criteria. The panel of experts was requested to provide suggestions in the remarks column if needed. The second criterion evaluated the content validity of the tool, i.e., whether the items in the scale assessed the concept they were expected to assess. The first and third criterion evaluated the consensual validity, i.e., the cultural relevance of each item to be used in the Sri Lankan context and whether each item has retained the conceptual meaning when translated into the Sinhala language, respectively.

Pre-testing

During the pre-testing phase, 12 PCOS women from different educational backgrounds and ethnicities were assessed using semi-structured interviews to evaluate clarity, comprehensibility of the instructions, response alternatives and content of the items of M-PCOSQ and to identify if there were questions that cause discomfort or distress to participants. The length of time taken to complete the questionnaire was also assessed.

Recruitment of participants

Administrative approval was obtained from the Ministry of Health and from director of the hospital where the study was conducted. Permission was obtained from the authors of the original M-PCOSQ to translate and validate their tool into Sinhala language. Informed written consent was obtained before all assessments.

A cross-sectional survey was carried out from October 2017 to January 2018 at the endocrine sub-fertility and gynaecology clinics at De Soysa Hospital for Women, Colombo, Sri Lanka. A convenient sample of 94 women aged 15-39 years diagnosed with PCOS, based on Rotterdam Revised

Diagnostic Criteria participated in the study (18). Women diagnosed with cognitive disabilities, psychiatric illnesses and endocrine disorders that can mimic PCOS such as Cushing syndrome, congenital hyperplasia, hyperthyroidism and hyperprolactinaemia were excluded from the study. Minimum required sample was calculated using the standard formula (19). For an expected correlation coefficient of 0.3, power of 80% and 5% level of significance, the minimum required sample was 85. An additional 10% was added for non-response rate. The final required sample was 94.

Instruments and measures

Socio-demographic and clinical data (age, monthly income, ethnicity, obstetric history, etc.) was obtained through a questionnaire developed by the researchers. The participants were requested to fill out the Sinhala version of the M-PCOSQ and the Sinhala version of Short Form Health Survey (SF-36) (20), whilst waiting to consult the doctor. M-PCOSQ has six domains, each relating to a frequent symptom of PCOS, namely hirsutism, emotions, infertility, menstrual problems, body weight and acne. Each question on the M-PCOSQ is associated with a 7-point Likert scale in which 7 represents optimal function and 1 represents the most dysfunctional level. Scoring was reversed for the positively stated items of 4, 10 and 27 in the Sinhala version of the M-PCOSQ. Lower mean scores on each domain indicate poor HRQoL. In the absence of another disease-specific PCOS questionnaire, the Sinhala version of SF-36 was used to establish the construct validity (20). This was developed by Ware and colleagues and consists of 8 health concepts, namely physical functioning, bodily pain, role limitation due to physical health problems, role limitations due to personal or emotional problems, emotional wellbeing, social functioning, energy/fatigue and general health perceptions (21). Scores of each item were transformed into a score 0-100 using a scoring key and items in the same scale are averaged together to create the 8 subscale scores. The lower the SF-36 score, the poorer the quality of life.

Reliability

Names and contact numbers of 10 participants who were willing to participate in the study after two weeks were noted down during the initial administration. A copy of M-PCOSQ was given to them in a sealed envelope. They were thoroughly explained not to open the envelope before being contacted over the telephone. After two weeks, these participants were contacted by telephone and requested to answer the questionnaire in the sealed envelope. On the same day, the answers given by them were recorded over the phone. Later the questionnaires were collected from the participants by personally meeting them or through the post. The test re-test reliability was evaluated by the interclass correlation coefficient computed using the data obtained on M-PCOSQ during the two administrations. Values between 0.6 and 0.8 designate 'adequate' agreement and values over 0.8 'excellent' agreement (22). Internal consistency was assessed by Cronbach's alpha, with values of 0.67 and above being considered acceptable (23).

Validity

The data obtained on emotional wellbeing scale of SF-36 was used as this subscale appears to be quite like the defining elements of the emotion subscale of M-PCOSQ. Therefore, to assess the convergent validity of M-PCOSQ, Pearson's correlation test was conducted for the scores of all subscales of M-PCOSQ and the scores of the emotional wellbeing of SF-36. It was hypothesized that the psychological wellbeing domain of the SF-36 would correlate more strongly with the emotional disturbances subscale of M-PCOSQ than any of its other five subscales. A correlation value of 0.4 was considered satisfactory (24). As there were no agreed upon suitable tools to be used to assess divergent validity, that was not done.

Results

In the forward translations, back translation and the consensual-related validation process, several items in the original instrument had to be modified for the Sinhala version. In the Sinhala version, the items 4,

10 and 27 were stated as positive statements to increase the accuracy of the responses. Hence, a reversed scoring system was adopted to score these three items. The first modified Delphi round yielded an acceptable rating for all items (a rating of 7 or more). However, the experts of the Delphi panel suggested amendments for the items to retain the conceptual meaning. Therefore, the Sinhala translation of M-PCOSQ was reviewed when an item was rated 7-9 by all experts. The second version with the amended items was mailed to the panel of experts for reevaluation. As all the items received a rating of 7 or more and no further amendments were there in the second round, the final version of the translated M-PCOSQ was synthesized. This was then pre-tested. During the pre-test, participants did not encounter any difficulty in comprehending and answering the questions. Therefore, it was concluded that the questionnaire can be subjected to further analysis of its psychometric properties such as construct validity, internal consistency and test-retest reliability.

Table 1 presents the socio-demographic and clinical characteristics of the sample (N=94). The mean age of the sample was 27.13 (SD=5.12) years. The majority of participants were Buddhists and 39.4% had studied up to G.C.E Advanced Level. Most of the participants were married and 77.1% reported infertility (Table 1).

Reliability

The internal consistency and test-retest reliability are represented in Table 2. All subscales except weight and menstrual problems demonstrated satisfactory internal consistency ($\alpha=0.67-0.96$). The interclass correlation coefficients were higher for all the subscales (0.97 or above), demonstrating excellent test-retest reliability ($p<0.01$) (Table 2).

Validity

The convergent validity was evaluated by the correlation between emotional wellbeing scale of the SF-36 and the emotions scale of the M-PCOSQ. Table 3 shows a satisfactory significant positive correlation between related subscales of the two instruments. Emotions scale of the M-PCOSQ correlated with the

psychological wellbeing on the SF-36 ($r=0.63$; $p<0.01$) and this showed a stronger correlation compared with the correlation to the other five domains, namely hair ($r=0.197$; $p=0.57$), weight

($r=0.284$; $p<0.01$), infertility ($r=0.386$; $p<0.01$), menstrual problems ($r=0.38$; $p<0.01$) and acne ($r=0.08$; $p=0.446$) (Table 3).

Table 1: Socio-demographic and clinical characteristics of the sample (N=94)

Characteristic	No. (%)
Ethnicity	
Sinhala	58 (61.7)
Tamil	21 (22.3)
Muslim	15 (16.0)
Religion	
Buddhist	54 (57.4)
Hindu	11 (11.7)
Islam	15 (16.0)
Roman Catholic/Christian	14 (14.9)
Marital status	
Married	68 (72.3)
Unmarried	24 (25.5)
Widowed/ divorced	2 (2.2)
Highest educational level	
Below grade 11	15 (16.0)
G.C.E Ordinary Level	35 (37.2)
G.C.E Advanced Level	37 (39.4)
Diploma	2 (2.1)
Bachelor's degree	4 (4.3)
Master's degree	1 (1.1)
Monthly income of the family	
Rs 5000-10,000	6 (6.4)
Rs.10,001-20,000	22 (23.4)
Rs.20,001-40,000	41 (43.6)
Rs.40,001-60,000	20 (21.3)
Rs. 60,001-80,000	4 (4.3)
Rs. 80,001-10,0000	1 (1.1)
Pregnancy status **	
Currently pregnant	1 (1.4)
Currently not pregnant	69 (98.6)
Number of children **	
No children	54 (77.1)
1 child	8 (11.4)
2 children	5 (7.1)
3 children	3 (4.3)

Duration of years trying to conceive***	
Less than a year	13 (24.1)
1-2 years	18 (33.3)
3-4 years	10 (18.5)
More than 4 years	13 (24.1)
Subfertility treatment ***	
Currently on treatment	52 (96.3)
Currently not on treatment	2 (3.7)
History of abortion or stillbirth	
Present	12 (17.1)
Absent	58 (82.9)

*Age range: 18 to 39 years

** Total number of married, divorced and widowed (n=70)

*** Total number of married women with no children (n=54)

Table 2: Internal consistency and test-retest reliability of the six domains of the M -PCOSQ

Sinhala version

Domain	Cronbach alpha	Interclass
Emotions	0.67	0.98**
Body hair	0.96	0.97**
Weight	0.46	0.99**
Infertility	0.8	0.99**
Menstrual problems	0.33	0.98**
Acne	0.92	0.99**

** Significant at 0.01 level (2 tailed)

Table 3: The convergent validity of M-PCOSQ Sinhala version

Measure (M-PCOSQ)	Emotional well-being scale (SF-36)
Emotions	0.63**
Body hair	0.2
Weight	0.28**
Infertility	0.39**
Menstrual problems	0.38**
Acne	0.08

** Significant at 0.01 level (2 tailed)

Discussion

The rigorous translation procedure ensured that the M-PCOSQ Sinhala version has adequate cultural and conceptual equivalence. High ratings of the modified Delphi process indicated adequate content and consensual validity of the M-PCOSQ Sinhala version. The test-retest reliability of the Sinhala version of the M-PCOSQ was found to be high. All subscales achieved high correlations greater than 0.7, which indicates that the questionnaire generates constant results from subjects at different points of time, in the absence of evidence for a change in the existing health status. This finding is in accordance with the previous studies (10-12). Internal consistency assesses the extent to which individuals with a higher score on one item have a higher score on the other items in the same domain (4). The internal consistency of the M-PCOSQ Sinhala version was high except for the weight and menstrual problem domains. When we analysed individual questionnaires, it was found that participants have not shown consistency in answering the questions that fall under these two domains. For example, women with high BMI have stated that they are not concerned about being overweight and had never felt that their partners perceived them as unattractive. At the same time, they have stated that they have difficulty staying at their ideal weight and had trouble dealing with weight only because they were advised to lose weight by their health care professionals. A community-based study conducted in Sri Lanka by Kumarapeli and colleagues has also reported that the prevalence of obesity among PCOS women was 43.8% (Asian cut-off) and 17.8% (Western cut-off). However, only 30.8% of those with $BMI \geq 30 \text{ kg/m}^2$ and 22% of those with a $BMI \geq 25 \text{ kg/m}^2$ perceived themselves as obese. These findings highlight the socio-cultural influence on the perception of obesity and the need for addressing these biased perceptions in the management of PCOS (14). Furthermore, we found that most of the participants have given a lower rating for irregular menstrual periods and menstrual cramps indicating a lower HRQoL. At the same time, they have given a higher rating for headaches and abdominal bloating as they do not frequently experience these symptoms during their

menstruation. Internal consistency or inter-item correlation measures the extent to which individuals with a high score on one item have a higher score on the other items in the same domain. Thus, the above discrepancies in their responses to the items in the weight and menstrual problem domains have contributed to the low internal consistency. Meanwhile, the 'menstrual problem' domain demonstrating the lowest Cronbach's alpha value was reported by other researchers (4, 9, 25-26) where some have suggested a further analysis of the menstrual scale (25-26).

The convergent validity was adequate as a statistically significant correlation was observed between emotions (M-PCOSQ) and psychological well-being (SF-36) ($r=0.629$; $p<0.01$). This was stronger than the correlation between the other subscales of M-PCOSQ and psychological well-being scale of the SF-36. This finding mirrors the findings of the previous validation studies (6-7, 12, 26).

One of the key strengths of the study is that it established the validity and reliability of a disease (PCOS) specific tool to assess HRQoL in women with PCOS, which was previously unavailable in Sri Lanka. The main limitation of this study is that all patients were recruited from a single government hospital in Colombo. Consequently, it could be argued that this affects the generalizability of the findings to the entire community of women in the general population diagnosed with PCOS. Since the participants included in the study were selected from an endocrinology clinic, a subfertility clinic and a gynaecology clinic when presenting with differing manifestations of PCOS, it could be argued that there was no selection bias that affected the quality of the validation process. Nevertheless, further research may need to be conducted with a larger sample including other districts of the country with various education and socioeconomic status. Such studies would extend the generalizability of the M-PCOSQ Sinhala version. The present study has a few other limitations as well. Retest among 10 participants may not be adequate and, the retest was not administered by an interviewer similar to the study proper which are limitations. The factorial structure and responsiveness of M-PCOSQ Sinhala version were not evaluated in

the present study. Future studies should investigate the capacity of the M-PCOSQ Sinhala version to assess the health status of those with PCOS and to detect the changes in their HRQoL due to treatment.

Conclusions & Recommendations

M-PCOSQ Sinhala version is a valid and reliable tool to measure HRQoL of PCOS women in Sri Lanka. This study will enable the clinicians and researchers to assess the health-related quality of life of women with PCOS using a validated disease-specific questionnaire in the vernacular. Thus, it is recommended that this questionnaire be used in clinic settings and psycho-social research related to PCOS as a screening instrument measuring HRQoL in women with PCOS.

Public Health Implications

- In the absence of a disease-specific questionnaire to assess the quality of life of women with polycystic ovary syndrome, this study was done to validate and assess reliability of the modified polycystic ovary syndrome health-related quality of life questionnaire in Sinhala language (M-PCOSQ Sinhala).
- The M-PCOSQ Sinhala has high content, consensual and convergent validity and test-retest reliability with good cultural and conceptual equivalence. It can be recommended for use in clinic settings and psycho-social research.

Author Declarations

Competing interests: Authors declare that they have no conflicts of interests.

Ethics approval and consent to participate: Ethics clearance was obtained from the Ethics Review Committee, Faculty of Medicine, General Sir John Kotelawala Defence University, Sri Lanka (RP/2017/10).

Funding: The study is not supported or sponsored by any commercial organization, funds or grants.

Acknowledgements: Authors wish to thank Professor Louise Dye for granting permission on behalf of her research team for us to use M-PCOSQ. We also wish to thank the director, medical officers, and the nursing sisters of De Soysa Hospital for Women, Sri Lanka for their cooperation.

Author contributions: BAR carried out the literature review, contributed to the design of the study, did data collection, completed statistical analysis and contributed to writing the manuscript. CNW contributed to designing the study and writing the manuscript. AB contributed to designing the study, statistical analysis of data and writing the manuscript. NJF contributed to designing the study. All authors went through and contributed to the final draft of the paper.

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